IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
MALLINCKRODT PLC, *et al.,*	)	Case No. 20-12522 (JTD)
	)	(Jointly Administered)
Debtors.	)	
	)	**Re: D.I. 2159 and 3529**

OPINION[1] AND FINAL ORDER

The price of prescription drugs in the United States has generated a great deal of attention from government officials, the media and parties who must pay what they consider to be unreasonably high prices for medications. At times these high prices lead to litigation against drug manufacturers. Debtors, who produce one of the most expensive drugs in the U.S., are one of those manufacturers.

Prior to filing for bankruptcy protection, Debtors had been sued by numerous parties over the price of their drug, HP Acthar Gel ("**Acthar**"). Acthar was first approved for use in the United States nearly 60 years ago. Until 2003, Acthar sold for less than $1000 per vial. By 2019, it was selling for nearly $40,000 per vial. Certain third-party payors, who are referred to in this proceeding as the Acthar Insurance Claimants ("**AICs**"), sued Debtors prepetition, and filed proofs of claims for prepetition purchases of Acthar, as well as proofs of claims for administrative expenses based upon post-petition purchases, along with a motion for an order allowing the administrative expense claims.[2] Debtors objected to the Administrative Expense

[1] This opinion shall constitute the Court's findings of fact and conclusions of law as required by Federal Rule of Civil Procedure 52 as made applicable by Federal Rule of Bankruptcy Procedure 7052.

[2] D.I. 2159, Motion for Entry of an Order Allowing and Compelling Payment of Administrative Claims Pursuant to 503(b) of the Bankruptcy Code (the "**Motion**").

Claims.[3] Following denial of Debtors' Motion for Summary Judgment,[4] I conducted a two-week bench trial to determine the validity of the AICs' Administrative Claims.

Charging a high price for a prescription drug is not, in and of itself, illegal. The United States provides limited controls over the pricing of drugs and, generally speaking, a manufacturer is free to charge whatever price it thinks the market will bear. To prevail on their claims, therefore, the AICs needed to prove that Debtors' ability to charge a supracompetitive price resulted from some other illegal activity. The AICs, therefore, claim that the price of Acthar was unreasonably high because of Debtors' anti-competitive conduct in violation of the Sherman Act, and their illegal payments to certain charities and doctors in violation of the RICO Act (among other laws) in order to boost sales of Acthar. Having reviewed the extensive evidence submitted at trial, I conclude that the AICs have failed to meet their burden of proof on either of these allegations. Therefore, for the reasons I will explain, the AICs' Motion is denied and the Debtors' Objection to the Administrative Claims is sustained.

FACTS

I. The History of Acthar and Synacthen

The antitrust claims here revolve around two drugs: Acthar and Synacthen Depot ("**Synacthen**"). The first, Acthar, is a drug manufactured and sold by the Debtors. Acthar is a naturally derived, long-acting complex mix of peptides that includes the full natural human ACTH 1-39 amino acid chain along with additional peptides.[5] It was approved for sale in the United States by the FDA in 1952 and is currently approved to treat 19 conditions or "indications."[6] For one of these conditions, infantile spasms ("**IS**") Acthar is a first line

[3] D.I. 3529, Debtors' Objection to Certain Acthar-Related Administrative Claims (the "**Objection**").
[4] D.I. 4792.
[5] DX1; Pretrial Order Stipulated Facts ¶ 19.
[6] AICX0091.

treatment, meaning it is typically the first drug prescribed to treat the condition. For all other indications, it is a second-line or later treatment, meaning it is not the first drug prescribed to treat a condition and is prescribed only after other treatments have failed.[7] Acthar is not covered by a patent, but its manufacturing process is a trade secret.[8]

There is no generic or non-brand name version of Acthar, but there are synthetic ACTH products. Synthetic ACTH products contain 24 of the 39 amino acids found in naturally occurring ACTH. Some of the synthetic ACTH products are short-acting, not long-acting like Acthar, and are approved only for diagnostic use, not therapeutic use, meaning they are approved for use in diagnosing a condition, but not treating it. Cortrosyn is an example of a short-acting synthetic ACTH that is on the market for diagnostic purposes.[9]

While several long-acting synthetic ACTH products have been developed, none have been approved for use in the U.S.[10] One such product, the other drug at the center of this case, is Synacthen. The active ingredient in Synacthen and other long-acting synthetic ACTH products is simply synthetic ACTH 1-24, also known as cosyntropin or tetracosactide.[11] Synacthen is approved for sale in over 40 countries to treat several conditions (many of the same ones for which Acthar is used) but is not approved in the U.S. Synacthen has no patent or trade secret protection.[12]

II. Mallinckrodt's Acquisition of Acthar and the U.S. Rights to Synacthen

Acthar was owned by Sanofi (now Aventis) until it was purchased by Questcor Pharmaceuticals, Inc. in 2001.[13] Questcor was struggling to make a profit from its sales of

[7] 11-15-21 Transcript at 143.
[8] Pretrial Order Stipulated Facts ¶ 27.
[9] Pretrial Order Stipulated Facts ¶ 35; 11-17-21 Transcript at 31-32.
[10] DX 359; Pretrial Order Stipulated Facts ¶¶ 34-36.
[11] 11-10-21 Transcript 45, 54, 112.
[12] Pretrial Order Stipulated Facts at ¶¶ 34-56.
[13] Pretrial Order, Stipulated Facts at ¶ 28.

Acthar. Then, in 2003 Acthar received orphan drug designation for IS, though it was not yet approved for that condition. With that designation, and following a change in leadership, Questcor implemented a new aggressive pricing strategy for Acthar and the price jumped from $902 per vial in 2003 to over $23,000 in 2007.[14] In October of 2010, Acthar was approved to treat IS and obtained orphan drug exclusivity for that condition until 2017.[15] Questcor continued to increase the price of Acthar until 2012, when the price reached $28,686.[16]

In the years leading up to 2013, Questcor had been monitoring Synacthen, which was then held by Novartis, as a potential competitor to Acthar.[17] Novartis held global development rights for Synacthen, but never developed it for sale in the U.S., determining that it would be too time-consuming and costly to do so. It decided to auction off the U.S. rights to Synacthen instead.[18]

When Questcor learned that Novartis was shopping the U.S. rights to Synacthen, it acted quickly to bid on those rights. Questcor outbid the competing bidders, Retrophin and Marathon, and secured the license for $135 million ($300 million with the annual milestone payments included).[19] The license provided Questcor with the Synacthen formulation, trademark, post-marketing safety data, manufacturing know-how, and toxicology studies.[20]

Although Questcor's agreement with Novartis included "mechanisms to ensure that Questcor pursue[d] FDA approval and commercialize[d] Synacthen upon approval,"[21] the acquisition -- being one by a competitor of a potentially competing product -- drew the attention

[14] AICX 109.
[15] AICX0091.
[16] AICX0091
[17] AICX-499.
[18] DX 162.
[19] AICX-79, DX 220.
[20] 11-10-21 Transcript at 60; AICX0091
[21] AICX 78

of the Federal Trade Commission (the "**FTC**"). Only a month after the Synacthen acquisition, the FTC opened an investigation "to determine whether the acquisition may substantially lessen competition and thereby violate federal antitrust laws."[22] The FTC action was resolved a few years later, as discussed below.

Around the same time that Questcor acquired the Synacthen license, the Debtors had also begun to conduct diligence regarding the potential acquisition of Questcor. In November of 2013, Mallinckrodt's investment banker, Barclay's, delivered its preliminary assessment of Questcor to Mallinckrodt's management.[23] The Barclay's Report highlighted Acthar as Questcor's "Key Product" and noted that upon acquiring Acthar, Questor had increased its manufacturing capacity and increased the price from $1650 per vial to $28,686 per vial. It also noted that "Acthar is not protected by any patents . . . but multiple barriers to entry related to formulation, manufacturing and regulatory make generic synthetics competition less likely."[24]

The Barclay's presentation also discussed Questcor's recent acquisition of Synacthen, noting there were "immaterial U.S. sales and long projected timeline to U.S. launch."[25] It went on to list the Synacthen acquisition as one of the barriers to entry for Acthar competition, describing Synacthen as "Questcor's main source of potential competition."[26] The Barclay's presentation listed the Synacthen acquisition as one of two defensive moves recently made by Questcor, along with Questcor's acquisition of BioVectra, Questcor's manufacturing partner for the active ingredient in Acthar. As Barclay's explained, the BioVectra acquisition "secured key manufacturing process trade secrets relating to Acthar."[27] The presentation went on to describe

[22] AICX-349
[23] AICX 91.
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*

the Synacthen acquisition as "a defensive move to acquire a potential future competitor" and noted that it "removes the overhang of potential franchise erosion due to future competition…."[28]

The Debtors' internal due diligence came to similar conclusions about Questcor, describing Acthar as a "protected franchise" due to the complicated formulation, manufacturing, and regulatory requirements and suggesting that Questcor had "walled off possible weaknesses by acquiring … Synacthen."[29] Mallinckrodt's internal diligence presentations also state that the Synacthen acquisition could "control introduction [of Synacthen] into the U.S. market" and assume that Acthar would "face no competitive threat in the future from synthetic ACTH" under any forecast scenario.[30]

Mallinckrodt's diligence into Questcor also highlighted legal actions and governmental investigations against Questcor, which included the FTC probe, and investigations by the US Attorney's Offices for Pennsylvania and New York, as well as the SEC regarding Questcor's promotional practices related to Acthar with potential fines in the range of $200-400 million. Mallinckrodt's Audit Committee characterized the FTC probe as "a medium risk to achievement of deal value."[31]

With these risks in mind, the Debtors' board voted to proceed with the acquisition and the transaction closed in August of 2014, in a deal worth approximately $5.8 billion.[32]

III. Development of Synacthen and other Synthetic ACTH Products

Thus, by the end of 2014, Mallinckrodt owned both Acthar and the U.S. rights to Synacthen. Since Questcor's agreement with Novartis required it to try to use commercially

[28] *Id.*
[29] AICX 103, AICX 106.
[30] AICX 109; AICX 92.
[31] AICX 103.
[32] AICX 1442.

reasonable efforts to develop and commercialize Synacthen and included milestone deadlines for doing so, it had begun working on developing Synacthen promptly after the acquisition. Questcor quickly discovered that it got less than it had bargained for from Novartis.[33]

Among other things, Questcor learned that there were problems with both Synacthen's drug substance (the drug's active pharmaceutical ingredient or "**API**") and manufacturing that would need to be resolved before any effort to obtain FDA approval could begin. Within a few months of the acquisition of Questcor, Debtors found themselves in the position of having to find a new manufacturer for Synacthen, a process which was delayed by the then current manufacturer's slow release of the necessary records. While they were able to secure a new manufacturer by June of 2014, it was not until October of 2015 that that manufacturer was able to produce an "initial engineering batch" and not until February 2016 that it was able to produce batches for use in clinical trials.[34]

In the meantime, the Debtors needed to determine which indications or medical conditions they would pursue for Synacthen. With the knowledge that Synacthen's approval for any indication for which Acthar was already approved would significantly affect Acthar's sales, the Debtors considered multiple options, all of which would "extend Acthar's lifecycle."[35] In several internal emails, the Debtors' employees expressed concern about bringing Synacthen to the market for any indication. In February of 2016, Josh Schafer, the Debtors' Chief Strategy Officer, prepared a report entitled "Synacthen Scenarios & Assumptions" in which "it is assumed that Synacthen would gain greater than 50% of IS patient share."[36] The report further calculated

[33] DX 230, DX 231, DX 235, DX 227, DX 317.
[34] DX 499, DX 675.
[35] AICX 484.
[36] AICX1302.

the cash impact of a Synacthen launch, concluding that a difference of just two years would result in a benefit to Mallinckrodt of potentially hundreds of millions of dollars.[37]

The Debtors ultimately decided to pursue approval for a disease called Duchenne's muscular dystrophy ("**DMD**"), a decision that Mallinckrodt's Chief Scientific Officer, Dr. Steven Romano testified was driven by several factors. Clinically, the Debtors decided on DMD because it was a disease affecting adolescent boys for which there were currently few treatment options and because the data regarding the ways in which Syncathen works in the body suggested that Synacthen might be particularly effective.[38] But the Debtors also chose DMD because they believed they could get orphan drug status for Synacthen if it were approved for this indication, which would give the Debtors exclusivity for several years and enable them to price Synacthen at a higher level than it was priced outside of the U.S. -- roughly $300,000 per year.[39] Debtors knew that obtaining approval of Synacthen for DMD had a low probability of success (about 15%), but as Dr. Romano and others testified, the probability of the FDA approving any drug is relatively low.[40]

While working to get Synacthen approved to treat DMD, the Debtors were also conducting clinical research and market studies to understand the differences between Acthar and Synacthen with the goal of helping both physicians and their own commercial team understand the distinctions between the products.[41] Some of the market research the Debtors had conducted showed that physicians believed Synacthen and Acthar to be clinically similar and therefore if the Debtors failed to differentiate the two products, Acthar sales might quickly

[37] *Id.*
[38] 11-10-21 Transcripts at 55-57, 88, 89.
[39] 11-10-21 Transcript at 11.
[40] See, e.g., 11-10-21 Transcript at 10-11, 77.
[41] 11-10-21 Transcript at 19- AICX568, AICX-557.

decline in favor of Synacthen sales.[42] Accordingly, the Debtors undertook a "full scrub of data to remove any use of Synacthen data in reference to Acthar."[43]

During the same time that the Debtors were working on getting Synacthen approved for treatment of DMD, the losing bidders for the Novartis license – Retrophin and Marathon – also began to work on getting a synthetic ACTH product to market. The Debtors' possession of the rights to Synacthen did not prevent others from developing a competing long-acting synthetic ACTH formulation. There was no IP protection on Synacthen, and its active ingredient was relatively easy to reproduce.[44]

Retrophin launched its development efforts immediately after losing its bid for Synacthen. On June 13, 2013, following its failed auction bid, Retrophin's CEO observed that losing the auction was a blessing in disguise, stating "Synacthen was off-patent. The API [active pharmaceutical ingredient] is readily available. We can secure API, formulate the product, file for orphan status, run the trial we intended to run, all without Novartis…. [W]e might even save time given Novartis is still upgrading their CMC and their fill-finish plan is not FDA approved."[45]

By December 2014, Retrophin was able to formulate its own synthetic ACTH product and manufacture "proof of concept" batches.[46] Retrophin sought FDA approval of its product for use in treating infantile spasms and nephrotic syndrome.[47] However, it abandoned the project at the clinical trial stage.[48]

[42] 11-8-21 Transcript at 144-45; AICX 546
[43] AICX-554, AICX 555.
[44] 11-12-21 Transcript at 97-98, 101.
[45] DX 331.
[46] DX 341 at 1, 5.
[47] 11-17-21 Transcript at 91.
[48] 11-17-21 Transcript at 34.

Marathon likewise began working on a synthetic ACTH shortly after it lost the Novartis bid, a project that was later sold to West Therapeutics, Inc.[49] West was also seeking approval of its product for treatment of infantile spasms.[50]

These last few events – the development and manufacturing efforts of the Debtors, Retrophin, and Marathon/West all took place in the three plus years after Questcor acquired the Synacthen license in 2013. As previously noted, shortly after that transaction closed, the FTC launched an investigation into whether the acquisition of the Synacthen license violated antitrust laws. As all the events from 2013 through 2016 unfolded, the FTC continued its investigation and in 2017, the parties reached a settlement. In addition to a $100 million fine, the settlement required the Debtors to (1) sublicense certain of the rights to Synacthen to a third party, royalty free and with an indefinite term, to develop Synacthen and seek approval for use in treating infantile spasms and nephrotic syndrome; (2) provide the sublicensee with all rights and information it had received under the license with Novartis, as well as the Debtors' improvements upon those assets, (3) fulfill contractual obligations to pay Novartis; and (4) file annual reports with the FTC.[51] The FTC approved Marathon (later West) as the sublicensee.

So, although Marathon/West had already begun working on a synthetic ACTH, by 2017 it had received all the Synacthen assets that the Debtors had received from Novartis. West ultimately sought FDA approval for its synthetic ACTH product, Cosyntropin, for a diagnostic indication using what is commonly referred to as a "505(b)(2) application."[52]

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[49] Burke Deposition transcript at 34-35, 175-177; 11-17-21 Transcript at 35-39.
[50] 11-17-21 Transcript at 94.
[51] AIXC 0819.
[52] 11-17-21 Transcript at 36. Burke Deposition at 176-78. A 505(b)(2) application is a somewhat abbreviated route to obtaining drug approval by the FDA because it allows an applicant to rely on the data of an already approved product if it can establish that its product and the already-approved product are similar enough that new data is not necessary. Establishing this connection between the new drug and the already approved drug is referred to as a "bridge". Burke Deposition at 63.

West, using both its own data and the data it received from the Debtors, tried to get approval for Cosyntropin, but following feedback from the FDA regarding the difficulty it would likely encounter in establishing the necessary bridge, West ultimately decided to abandon its attempts to bring a synthetic ACTH product to market.[53]

The Debtors, however, were continuing their efforts to get Synacthen approved, working through the various stages of clinical trials. It was then that they began to encounter more difficulties. First, the FDA approved a new drug for DMD, which was priced significantly lower than Synacthen's anticipated price. This drastically changed the economics of the Synacthen project for the Debtors and they decided to write off the value of Synacthen entirely.[54] Debtors continued to work on getting Synacthen approved for DMD for another year, since they had committed to the DMD patients and medical community to use best efforts to complete the studies, but they encountered what they viewed to be insurmountable problems in enrolling patients for the necessary clinical trials.[55] Accordingly, in December of 2019, Debtors abandoned the project.

As Dr. Romano testified, there were multiple considerations, including commercial, regulatory, legal, and practical ones that informed the Debtors' decision not to do anything further with Synacthen at that point in time.[56] There were also financial concerns. Management was informed by Hillary Muldoon, Debtors' head of competitive intelligence, that "a potential launch of [Synacthen] in any therapeutic indication will have a negative impact on the Acthar business."[57] Following their decision to cease development of Synacthen, on July 14, 2020, the

[53] 11-17-21 Transcript at 37-38; 11-12-21 Transcript at 123-125.
[54] 11-10-21 Transcript at 12-13, 15.
[55] 11-10-21 Transcript at 80-82.
[56] 11-10-21 Transcript at 18.
[57] AICX-303.

Debtors notified Novartis that they were unilaterally and permanently suspending all remaining rights to develop Synacthen.

At this point in time, no one is pursuing the development or marketing of Synacthen or any synthetic ACTH. However, there is one company, ANI Pharmaceuticals, Inc., that was working on reviving a previously approved, but lapsed, non-synthetic natural ACTH product. On November 1, 2021, ANI obtained FDA approval for its product, Purified Cortrophin Gel, for the treatment of acute exacerbations of MS, rheumatoid arthritis, and nephrotic syndrome.[58] ANI's product is expected to hit the market in 2022 and will compete with Acthar.[59]

IV. Acthar Pricing

Over the years, the Debtors have considered making changes to Acthar's pricing structure multiple times. By early 2020, following the entry of a $650 million judgment against the Debtors by a D.C. Court on claims made by the Centers for Medicare and Medicaid Services ("**CMS**") regarding rebates owed to the federal government due to increases in Acthar's price[60] and the continued negative publicity surrounding Acthar, Debtors again revisited the idea of changing Acthar's pricing structure. On April 30, 2020, Hugh O'Neill sent an email attaching a presentation called "Acthar Gel Pricing Options" in which the Debtors weighed "the financial realities of the company" against "the ability to shed the negative impact" that the pricing of Acthar has had on their corporate reputation.[61] The presentation concludes that "there is no scenario where a [price] reset results in a better financial outcome for the brand. The tradeoff

[58] DX 654.
[59] 11-10-21 Transcript at 52.
[60] See AICX 485
[61] AICX 320.

will come down to a choice between reduction of future risk and optimizing short term financial results."[62]

As Mr. Schafer, the Debtors' Chief Strategy Officer explained in May of 2020, "Acthar appears more 'Cash Cow' than 'Star'… we need to evaluate whether to divest or manage for cash. . . .Divesting Acthar could be beneficial because of its impact on capital and negative growth profile, and remove perceptual overhang. However, our ability to transact at a reasonable value is dependent on cleansing Acthar of its liabilities."[63] Ultimately, the Debtors decided not to change the price of Acthar.

V. Acthar Co-Pay Subsidies

As the price of Acthar steadily increased, Questcor developed relationships with certain non-profit organizations that provide co-pay assistance to patients who cannot afford their copays. As Kathleen Breton, the Debtors' Senior Director of Patient Services and Reimbursement testified, "most Medicare patients' Acthar copays are in the thousands of dollars" and "most Medicare patients end up requiring some form of financial assistance to pay for Acthar."[64]

In 2013, Questcor had been working with an entity called the Chronic Disease Fund ("**CDF**"), a non-profit organization that provides copay assistance for patients who cannot afford the full copay their insurer requires for a particular drug. In December 2013, in response to negative media attention regarding CDF's relationship with Questcor, CDF's president resigned, and the entire board was replaced. CDF subsequently closed the funds that covered Acthar as noncompliant with its new policies.[65]

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[62] *Id.*
[63] AICX-485.
[64] 11-8-21 Transcript at 173.
[65] AICX-417, AICX-94

When CDF closed its funds, Questcor moved its donations to two other foundations, the Caring Voice Coalition ("**CVC**") and The Assistance Fund ("**TAF**"). But by the end of 2015, CVC also terminated its relationship with Questcor, also because of negative media attention.[66]

Questcor, by now Mallinckrodt, continued its relationship with TAF, with whom it worked from 2014 until December 2020.[67] Debtors' donations were allocated across funds for multiple diseases. Before the Debtors started donating to TAF, TAF did not cover copays for Acthar.[68]

Internal emails at Mallinckrodt show that the company was aware that its donations to TAF increased Acthar sales. In an August 2015 email from the Debtors, an employee acknowledged that Mallinckrodt's relationship with TAF, or more specifically its donations to TAF, "significantly increase[d] sales of Acthar…"[69] From 2014 through 2017, the general manager of the Acthar business determined how much to donate to TAF.[70]

However, in 2017, following an industry-wide investigation into 501(c)(3) foundations that provide copay support, and the service of a civil investigative demand upon Debtors by the U.S. Attorney's Office for the District of Massachusetts, Debtors began to implement new policies and procedures regarding their relationships with copay assistance funds. They first transferred responsibility for relationships with these funds from their commercial department to their government affairs department.[71] In 2018, the Government Affairs department implemented a detailed standard operating procedure ("**SOP**") that considered the guidelines issued by the U.S. Department of Health and Human Services' Office of Inspector General (the

[66] AICX 533, 11-8-21 Transcript at 177-78.
[67] AICX-97
[68] Pretrial Order ¶ 103.
[69] AICX-162.
[70] 11-8-21 Transcript at 179-80.
[71] DX17.

"**OIG**") regarding how manufacturers can make donations to funds without violating the Anti-Kickback statute.[72] The Debtors' U.S. General Counsel, Mark Tyndall, testified that Debtors' agreement with TAF expressly incorporated the Debtors' SOP and included firewalls to ensure that the commercial business had no contact with anyone at TAF. Donation requests from TAF to the Debtors were unsolicited and due diligence was conducted to ensure that funds at TAF to which the Debtors' donations were allocated were "defined by reference to widely recognized clinical standards," "without limitation to symptoms, severity of symptoms, or disease stages," and "in a manner that are open to a broad range of products" as the OIG guidance required.[73] Debtors directed TAF to limit the amount of information and data provided to the Debtors to ensure that they could not correlate their contributions to the amount of co-pay assistance provided to Acthar patients.[74]

While Debtors established a Patient Foundation Charitable Contributions Committee to oversee and approve TAF donations, it does not appear that the committee operated in any formal capacity. As Mr. Tyndall testified, the committee did not hold formal meetings, keep minutes, or have bylaws, and they communicated largely by email.[75]

Between 2014 and 2020, the Debtors donated over $120 million to TAF. Over the years, the Debtors had discussed ceasing donations to TAF, but observed that doing so "would have a negative impact of tens of millions of dollars per year on Acthar's net sales."[76] Ultimately, the Debtors decided to stop donations beginning in 2021 because of "concerns about potential legal exposure of continuing to make those donations."[77] When the Debtors did cease donations, they

[72] DX 002.
[73] 11-9-21 Transcript at 94.
[74] 11-9-21 Transcript at 80, 91, 92, 94, 101-103.
[75] 11-9-21 Transcripts at 63-64.
[76] 11-9-21 Transcripts at 155-156.
[77] 11-9-21 Transcript at 153.

saw "an uptick in the number of patients that [they] sent to [their] free goods programs … because the funding wasn't available at The Assistance Fund anymore."[78]

VI. Physician Speaker Program

During this time, the Debtors also worked to increase their efforts to market Acthar by hosting speaker programs to educate healthcare professionals about Acthar. The goal of these programs was to increase sales of Acthar.[79] Like with copay fund contributions, the Debtors also have policies in place regarding their speaker programs to prevent abuse.[80] These policies require, among other things, that speakers have a contract in place and are paid fair market value for their services, that speaking training meetings and programs be held in education-appropriate venues, that all meals provided in conjunction with such programs are modest and for a legitimate purpose, and that Debtors publish information about the payments they have made to physicians annually.[81]

Debtors use a third-party speaker program management firm called Veeva to manage logistics and provide Debtors with reports regarding compliance with their policies. Where non-compliance is alleged, it is investigated, and corrective action is taken where necessary.[82]

During the relevant time for this case, which is the post-petition period, the Debtors paid approximately $1.75 million to physicians for at least 443 speaker events and there are ongoing investigations into the Debtors' payments to healthcare providers in at least two states.

[78] 11-8-21 Transcript at 180-81.
[79] PTO at 19.
[80] DX 52, 55, 58, 62, 63, 67, 71 and DX677.
[81] DX 052, DX 062, DX 071 and 11-17-21 Transcript at 111-113, 121-22.
[82] 11-17-21 Transcript at 142-143.

ANALYSIS

I. Federal Antitrust Claims

The AICs assert administrative expense claims based on alleged antitrust violations by the Debtors under Section 1 and Section 2 of the Sherman Act during the post-petition period. In connection with Debtors' Motion for Summary Judgment, I concluded that there were material issues of fact regarding whether Debtors' conduct, either pre-petition or post-petition, constituted illegal conduct under the Sherman Act that allowed the Debtors to maintain a monopoly giving Debtors the ability to charge supracompetitive prices post-petition.[83]

Section 1 of the Sherman Act prohibits entering into agreements that unreasonably restrain trade. *LifeWatch Servs. v. Highmark Inc.*, 902 F.3d 323, 335 (3d Cir. 2018). "An 'unreasonable' restraint is one that inhibits competition in the relevant market." *Id.*

Section 2 of the Sherman Act prohibits the unlawful monopolization of trade. To establish a claim under Section 2, a plaintiff must prove that the defendant possesses monopoly power in the relevant market and that the defendant willfully acquired or maintained that power through exclusionary conduct. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307-08 (3d Cir. 2007).

In the Third Circuit, a private plaintiff seeking to establish a claim for damages under either Section 1 or Section 2 of the Sherman Act must first establish that it has antitrust standing. *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 264 (3d Cir. 1998) ("The question of standing is a threshold inquiry in all actions."); see also *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017) (same). Antitrust standing requires that the plaintiff prove that an antitrust injury was suffered by the plaintiff and that the plaintiff is an appropriate plaintiff to

[83] D.I. 4792.

bring the antitrust case. *Associated General Contractors of California, Inc. v. California State council of Carpenters*, 459 U.S. 519, n.31 (1983). Thus, the Debtors argue, the AICs had to prove that but for Questcor's acquisition of the Synacthen license, the FDA would have approved Synacthen for sale in the U.S., which would have created competition for Acthar in the market.

The AICs argue that the Debtors apply the wrong standard for establishing antitrust standing, or what they refer to as causation. They assert that I should apply the standard outlined in *Novell, Inc. v. Microsoft Corp. (In re Microsoft Corp. Antitrust Litig.)*, 699 F. Supp. 2d 730, 748. (D. Md. 2010), *rev'd in part on other grounds by Novell, Inc. v. Microsoft Corp.*, 429 Fed. Appx. 254 (4th Cir. 2011), that to satisfy the causation requirement a plaintiff need only show that the conduct at issue "contributed significantly to a defendant's continued monopoly power." Thus, the AICs argue, they only needed to present evidence that it was probable that a competitor armed with the Synacthen license would have obtained FDA approval absent Debtors' conduct. The AICs reliance on *Novell* is misplaced. As the *Novell* Court recognized, the "contributed significantly" standard is derived from the Federal Circuit's decision in *United States v. Microsoft*, 253 F.3d 54, 80 (Fed. Cir. 2001). The Federal Circuit specifically stated in its ruling that the "contributed significantly" standard applied in "equitable enforcement actions as opposed to actions for money damages." Therefore, I will apply the standard articulated by the Third Circuit in *City of Pittsburgh* and *Wellbutrin.*

In determining antitrust standing, the Third Circuit incorporated several factors set forth by the Supreme Court in *Associated General Contractors of California, Inc. v. California State Council of Carpenters*. 459 U.S. 519 (1983). Those factors were organized into the following multifactor balancing test by the court in *In re Lower Lake Erie Iron Ore Antirust Litig.* 998 F.2d

1144, 1165-66 (3d Cir. 1993): (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to prevent; (3) the directness of the injury; (4) the existence of more direct victims; and (5) the potential for duplicative recovery or complex apportionment of damages. Therefore, antitrust standing involves a two-part inquiry: (1) whether the plaintiff experienced an antitrust injury; and (2) whether the plaintiff is the proper plaintiff to bring the suit. In an antitrust case where the plaintiff is seeking damages, an antitrust injury is a necessary element of an antitrust claim. *See In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017) ("antitrust standing is more properly viewed as an element of an antitrust claim…"). Because I find that the AICs failed to carry their burden of proving a but for connection between the Debtors' conduct and their alleged injury, I do not need to address the remaining standing issues. *See City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) ("If antitrust injury is not found, further inquiry is unnecessary.")

Debtors rely on *City of Pittsburgh* to argue that antitrust standing does not exist when a plaintiff's grievance is caused by a regulatory scheme and not the defendant's actions. 147 F.3d 256, 266. In *City of Pittsburgh,* the City alleged an antitrust injury based on two power companies entering into a pre-merger agreement whereby one power company pulled its application to expand its services to additional zones in Pittsburgh. The City argued that the agreement lessened competition and raised prices. The court reasoned that the antitrust injury was too speculative as the lack of competition was due to a regulatory scheme and the City was merely "foist[ing] [its] version of what might have been on the court under the rubric of antitrust injury." *Id*. at 267. The court also concluded that there was a lack of facts regarding the

likelihood that the regulatory authority would have granted the withdrawing power company the approval it had requested.

Debtors contend that *City of Pittsburgh* is dispositive because the court rejected antitrust claims for lack of antitrust injury where "[t]he presence of the regulatory scheme and need for approval" serves to cut "the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise." 147 F.3d at 267-68. If no antitrust injury exists where it is unknown whether the regulatory authority would have granted a competitor approval because it never applied, then surely there can be no injury in a case where a competitor sought approval and was denied.

The AICs argue that *City of Pittsburgh* is inapposite because the court made clear that the ruling was specific to the era of regulated electric utility monopolies. At least one decision from the District of Delaware concluded that *City of Pittsburgh* did not apply in the context of a case involving the intersection of the Sherman Act and the Hatch Waxman Act. *In re Metoprolol Succinate Direct Purchaser Antitrust* Litigation, 2010 U.S. Dist. LEXIS 36303, at *21 (D. Del. Apr. 13, 2010). However, that decision was prior to the Third Circuit's decision in *Wellbutrin* where the Court recognized that "[i]n *City of Pittsburgh* we said that no antitrust standing exists when a plaintiff's grievance is caused by a regulatory scheme rather than by the defendant's actions." 868 F.3d at 166. I conclude that the *Wellbutrin* Court recognized the continuing validity of *City of Pittsburgh* and at least one court has recognized that the *Metoprolol* decision was superseded by *Wellbutrin*. *See United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1197 (N.D. Cal. 2017) (noting that *Metoprolol*'s rejection of the concept that certain regulatory requirements could be the cause of the antitrust injury instead of the defendant's conduct was superseded by the *Wellbutrin* and *Nexium* decisions).

In *Wellbutrin*, the appellants claimed that absent certain reverse settlement agreements, Anchen Pharmaceuticals would have launched a generic drug to compete with the defendant's drug. 868 F.3d at 165. The Court stated that the appellants had to show that the harm - increased drug prices for Wellbutrin XL -was caused by the settlement. *Id*. at 164-165. The court ultimately rejected appellants' argument because it did not account for a regulatory or legislative bar, holding that appellants' antitrust claims fail because the defendant's actions were not the actual cause of the appellants' alleged injury. *Id*. at 165-166. Moreover, the Court concluded that the appellants must produce evidence that it is more likely than not that Anchen Pharmaceuticals, would have obtained a license. *Id*. at 167. Evidence showing that another manufacturer may have obtained a license fails to meet this burden. *Id*.

In *Meijer, Inc. v. Biovail,* 533 F.3d 857 (D.C. Cir. 2008), the Court recognized the need for an antitrust plaintiff to prove that the defendant's conduct caused the alleged antitrust injury in the context of a regulatory scheme. The Court concluded: "a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm's exclusionary conduct." *Id.* at 862. The AICs assert that they have met that burden of proof. I disagree.

Debtors presented evidence at trial, through the expert testimony of Dr. Williams and Dr. Trish as well as the testimony of Mallinckrodt executives, that FDA regulatory requirements created significant barriers to the entry of Synacthen, or any other long-acting synthetic ACTH drug, into the market.[84] The documents submitted into evidence corroborate this testimony. For example, the documents show that before Questcor even acquired the Synacthen license, the

[84] See generally, e.g., 11-10-21 Transcript (Romano), 11-17-21 Transcript (Williams), 11-16-21 Transcript (Trish).

previous owner, Novartis, concluded that obtaining FDA approval for Synacthen in the U.S. was likely to be so fraught with challenges that it was not worth the effort.[85] Upon acquiring the Synacthen assets from Novartis, Questcor too began to see that what they had purchased was likely not going to be helpful in overcoming the anticipated FDA hurdles.[86] Even after they resolved the biggest unforeseen problem with the Synacthen assets – the fact that the existing Synacthen manufacturer was not FDA approvable– and were able to get a new manufacturer up and running, Questcor (later Mallinckrodt) encountered additional problems at the clinical trial stage that prevented it from satisfying the FDA's stringent requirements.[87]

Further, the problems that the Debtors encountered with the FDA approval process are not ones that are unique to them or ones that could be explained away by reference to their decisions along the way. The evidence at trial suggested that getting beyond the clinical trial stage of the FDA approval process is so difficult that the other manufacturers who sought approval of a synthetic ACTH product either also tried and failed at this stage or only sought approval in a manner that would avoid it entirely.[88] Even the AICs' own expert, Dr. Rheinstein—

[85] DX 162 (discussing possibility of pursuing FDA approval of Synacthen for MS indication and stating that "the team felt there were significant challenges to developing Synacthen as a commercially successful product in this modern era of FDA review and scrutiny compared with the 1952 approval of Acthar Gel in MS.").
[86] DX 231 (discussing change in FDA requirements that lowered the allowed limit of impurifications contained in peptides, stating "up until 2007, both FDA and EMA were allowing peptides to have [ ] limits of 0.2%, 0.5% and 1.0%. It is still allowed at those limits in the EU . . . However, in 2008, FDA started to push peptides to comply with the ICH limits for small molecules (unless justified), so it is now 0.05% report, 0.1% ID, and 0.15% qualified for API. . . Basically, that means that we will need to qualify (with existing tox data hopefully), the two new impurities at the very least."); DX 230 (discussing shortcomings in existing toxicology data); DX 235 (discussing problems Questcor uncovered with Synacthen's existing manufacturer, Takeda, stating "Takeda claims that they are not FDA approved (no problem) but more importantly are not suitable for an FDA inspection (big problem). They also claimed that their Synacthen production processes are complex and not a simple fill/finish operation (bigger problem). Moreover, they claim the production processes need to be developed further to be considered US commercial-ready. It looks as if we have uncovered yet another can of worms with regards to Synacthen CMC.")
[87] 11-10-21 Transcript at 80-82 (Debtors' Chief Scientific Officer discussing inability to satisfy FDA's clinical trial requirements because of difficulties finding patients willing to enroll in studies).
[88] 11-17-21 Transcript at 34 (noting Retrophin abandoned its attempts at FDA approval for its synthetic ACTH at the clinical trial stage); Burke Transcript (West's representative discussing risk associated with clinical trials and their use of a 505(b)(2) application to avoid the need for clinical trials); 11-10-21 Transcript at 77 (likelihood of any drug getting approval from the FDA is less than 10%).

who also described the rigorous FDA approval process─ concluded that he could only opine that Synacthen could have been approved for diagnostic use and not that it would have been approved because there are always other considerations, including whether the development of synthetic ACTH would make business sense.[89] I find this to be persuasive.

In addition to the persuasive evidence that the FDA regulatory process was the cause of the inability of either the Debtors or a potential competitor developing Synacthen or another long-acting synthetic ACTH product, the Debtors also presented evidence to refute the AICs' allegations that it was the Debtors' possession of the Synacthen rights that prevented or delayed the entry of a synthetic ACTH product to the market. Several witnesses testified that there was no IP protection for Synacthen, and it was relatively easy to reproduce.[90] Indeed, at least two other companies were able to do so without the Synacthen assets.[91] Further, even after the Debtors turned over the Synacthen assets to Marathon /West after the 2017 settlement with the FTC, West was still unable to obtain FDA approval for its synthetic ACTH product.[92]

All the evidence presented establishes that the FDA's drug approval requirements served as a barrier to the entry of a new synthetic ACTH drug to the market. As the *City of Pittsburgh* Court explained:

> [A]ntitrust injury must be caused by the antitrust violation-- not a mere causal link, but a direct effect. Here, the interposition of the regulatory scheme and actions of the parties -- both defendants and plaintiff -- interferes with the chain of causation. The statutory scheme precluded competition without the requisite regulatory permission. As Professors Areeda & Hovenkamp describe, "a plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event." Phillip E. Areeda

[89] 11-12-21 Transcript at 126.
[90] See *e.g.*, 11-12-21 Transcript at 97-98, 101; 11-10-21 Transcript at 29.
[91] 11-17-21 Transcript at 34, 37-38; 11-12-21 Transcript at 123-125; 11-17-21 Transcript at 31-39, 91-94 (discussing Retrophin and West's ability to formulate a synthetic ACTH without access to the Synacthen assets).
[92] Burke Deposition at 40 (testimony that none of the information West received was "adequately supportive to be meaningfully additive.").

& Herbert Hovenkamp, Antitrust Law P 363(b), at 222 (1995) (citing Axis S.p.A. v. Micafil, Inc., 870 F.2d 1105 (6th Cir. 1989)).

City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 268 (3d Cir. 1998) quoting 429 U.S. at 489. Just as the regulatory scheme present in *City of* Pittsburgh precluded competition in the utility market without the permission of the Public Utility Commission, here, the FDA precluded competition in the pharmaceutical market without its permission. This regulatory barrier broke the chain of causation and, accordingly, the AICs were unable to prove that the harm they experienced was connected to and in fact caused by the Debtors' alleged anticompetitive conduct. 147 F.3d at 267-68 ("The presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise."). For that reason, the AICs claims must fail.

Accordingly, I find that the AICs have failed to present sufficient evidence to support a conclusion that but for Debtors' acquisition of the Synacthen Assets a competitor would have developed either Synacthen or another long-acting synthetic ACTH product that could compete against Acthar. Having failed to prove a causal connection between Debtors' alleged illegal conduct and their damages, the AICs have failed to establish requisite standing to maintain a claim under the Sherman Act and, accordingly, an administrative claim under the Bankruptcy Code. Because the AICs lack standing, it is not necessary to address other antitrust elements, including damages.

II. State Law Antitrust Claims

In their administrative claim, the AICs alleged that the Debtors' conduct also violated numerous state laws. The AICs, however, failed to connect any evidence admitted at trial to the alleged state causes of action. Therefore, I conclude that the AICs have abandoned those claims *West v. Gregoire* , 336 P.3d 110, 113 (Washington Court of Appeals, 2014) ("When a party

asserts a claim in pleadings but at trial does not 'press' the claim in any way or present evidence to support it, the party abandons that claim."); *Harbison v. Little* , 723 F. Supp. 2d 1032, 1038 (M.D. Tenn. 2010) ("If a plaintiff fails to include arguments regarding a claim in a post-trial brief, the court is justified in finding that the plaintiff has abandoned that claim.").

III. RICO Claims

In their pre-trial brief, the Claimants argued that the Debtors violated the RICO Act through the Anti-Kickback Statute, False Claims Act, mail fraud, wire fraud, and the Travel Act. The AICs contend that the Debtors violated these federal statutes in two ways. First, the Debtors provided unlawful co-pay subsidies through donations to charitable foundations that provide co-pay assistance to eligible patients. Second, the AICs allege that the Debtors paid healthcare professionals, through speaker fees and other methods to persuade them to prescribe more Acthar. I will address each theory in turn.

A. RICO Standard of Review

To establish liability under the Racketeer Influenced & Corrupt Organizations Act ("**RICO**"), the plaintiff must show "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity, plus [(5)] an injury to business or property." *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 483 (3d Cir. 2015) (internal quotation marks and citations omitted). RICO defines "racketeering activity" as any one of an enumerated lists of different state and federal offenses, also known as predicates. *RJR Nabisco, Inc. v. Eur. Cmty.*, 579 U.S. 325, 329–30 (2016). "These predicates include "any act 'indictable' under specified federal statutes, §§ 1961(1)(B)–(C), (E)–(G), as well certain crimes 'chargeable' under state law, § 1961(1)(A), and any offense involving bankruptcy or securities fraud or drug-related activity that is 'punishable' under federal law, § 1961(1)(D)." *Id.* at 330. The plaintiff must show that the defendant committed a RICO

predicate act, otherwise the plaintiff's RICO claim fails. *See Heinemeyer v. Twp. of Scotch Plains*, 198 F. App'x 254, 256 (3d Cir. 2006).

Section 1964(c) of Title 18 of the U.S. Code provides a private right of action for "[a]ny person injured in his business or property by reason of [a predicate offense]." *Kenney v. Am. Bd. of Internal Med.*, 847 F. App'x 137, 146 (3d Cir. 2021). The plaintiff must "state an injury to business or property and 'that a RICO predicate offense not only was a but for cause of injury but was the proximate cause as well.'" *Kenney*, 847 F. App'x at 146 (quoting *St. Luke's Health Network, Inc. v. Lancaster Gen. Hosp.*, 967 F.3d 295, 300 (3d Cir. 2020)). Proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged." *Reyes*, 802 F.3d at 483 (quoting *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992)).

Therefore, the AICs had to prove that the Debtors committed a predicate act, and one of those predicate acts caused a direct injury to their business dealings. Based on their two theories, the AICs had to prove that either the foundation co-pay subsidy payments or the Debtors' physician payments were not only the but-for cause of their injuries but also the proximate cause of their injuries.

B. Claimants' Co-Pay Subsidy Theory of RICO Liability

Addressing the first argument, the AICs allege that the Debtors' systematic course of conduct in donating millions of dollars to co-pay assistance funds was for the purpose of increasing sales of Acthar. Thus, the Debtors violated the RICO Act when they made these payments post-petition. To prove this claim, the AICs had to demonstrate: (1) Debtors made post-petition contributions that violated the Anti-Kickback Statute; (2) Debtors committed mail or wire fraud by providing false certifications of compliance with specific fraudulent intent; and

(3) the purported violation caused injury to AICs' business or property during the post-petition period.

a. Anti-Kickback Statute

To violate the Anti-Kickback Statute a person or entity must "'knowingly and willfully' offer[] or pay[] 'any remuneration … to any person to induce such person … to refer an individual to a person for the furnishing … of any item or service for which payment may be made in whole or in part under a Federal health care program.'" *United States ex. Rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94–95 (3d Cir. 2018) (quoting 42 U.S.C. § 1320a-7b(b)(2)(A)). In their co-pay subsidy theory, the AICs allege that the Debtors violated the Anti-Kickback Statute because their intent in making the charitable donations was to induce more Acthar prescriptions for Medicare beneficiaries.[93] The AICs state that the Debtors only stopped donating millions of dollars to TAF at the end of 2020 because of "concerns of potential legal exposure of continuing to make those donations."[94]

Regarding the Anti-Kickback Statute, I find the AICs did not meet their burden. First, the AICs presented no evidence at trial of any post-petition contributions by the Debtors that were unlawful. The evidence shows that the Debtors' contributions were allocated to TAF disease funds that were independent, bona fide charitable assistance programs.[95] While the AICs state that the Debtors' compliance programs were "window dressing" to add a hint of legitimacy, there was no evidence establishing that the Debtors failed to follow their policies or the law during the post-petition period. In fact, the evidence at trial demonstrated the opposite. In one example, the AICs asserted in their pre-trial brief that the Debtors' Government Affairs

[93] D.I. 5553 at ¶ 81, pg. 39; D.I. 5553 at ¶ 85, pg. 41.
[94] D.I. 5553 at ¶ 87, pg. 42; 11-9-21 Transcript at 153.
[95] Pre-trial Order Stip. Facts at ¶¶ 93–94.

department did not conduct any diligence on the TAF relationship at the time of the transition from commercial. Instead, the evidence showed that the team conducted diligence over the ten months after the initial transition and before making its first recommendation to donate to TAF.[96]

Just because the Debtors' money flowed to TAF and was distributed to Acthar-related disease state funds in the post-petition period, does not mean the Debtors' contributions were illegal. Pharmaceutical companies, under OIG guidance, are allowed to make contributions to 501(c)(3) charitable foundations.[97] The AICs had to demonstrate that the Debtors' contributions were in some way unlawful.[98] From 2018 to 2020, Mallinckrodt donated $56.9 million to TAF.[99] The total amount of assistance TAF provided to Acthar patients was--$39.7 million.[100] TAF allocated the Debtors' contributions to various other disease funds including a juvenile arthritis fund that provided no assistance to Acthar patients and a fund for multiple sclerosis that used only 1.3% of total donations for Acthar.[101] Looking at all the funds in TAF that allocated Debtors' donations, Acthar was the subject of only 3.8% of claims for assistance and only 16.7% of the assistance provided.[102] Providing no evidence to contradict this, the AICs failed to prove the Debtors' contribution were unlawful.

Second, to prevail on their co-pay subsidy theory, the AICs needed to prove the Debtors committed mail or wire fraud by providing false certifications of compliance with specific fraudulent intent. *See United States v. Hedaithy*, 392 F.3d 580, 590 (3d Cir. 2004). However, the AICs provided no evidence and did not even attempt to show that Debtors provided false

[96] 11-9-21 Transcript at 85.
[97] DX 002 at 70,627; DX 005 at 31,121–22 n. 8.
[98] DX 603, TAF Donations and Assistance Data Compilation Tables.
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*

certifications of compliance and acted with the requisite specific intent to defraud them into covering excess Acthar prescriptions.

Finally, the AICs failed to establish that the alleged RICO predicate acts were the but-for cause of the alleged injury, as required in the Third Circuit. *See Anderson v. Ayling*, 396 F.3d 265, 269 (3d Cir. 2005). To establish the but-for cause, the AICs had to identify specific prescriptions that they would not have reimbursed but for the alleged fraudulent scheme. Instead, the AICs' expert did not even try to specify which prescriptions were aligned with Mallinckrodt's donations to TAF and failed to specify which prescriptions were associated with any illegal contributions. The AICs failed to provide evidence that even one prescription was the result of Mallinckrodt's TAF donations. The AICs have not met their burden of establishing that the Debtors violated the federal RICO statute through their donations to charitable foundations.

C. Debtors' Interactions with Physicians

Addressing their second argument, the AICs also alleged that the Debtors violated the RICO Act by paying physicians through speaker programs. They assert that the Debtors paid remunerations to prescribing physicians to induce them to prescribe Acthar and encourage other physicians to do the same. Thereby, the Claimants contend the Debtors violated the Anti-Kickback Statute, the False Claims Act, the federal Travel Act, as well as state bribery laws through these payments.

As previously stated, for me to find an Anti-Kickback Statute violation, a person or entity must "'knowingly and willfully' offer[] or pay[] 'any remuneration … to any person to induce such person … to refer an individual to a person for the furnishing … of any item or service for which payment may be made in whole or in part under a Federal health care program.'" *U.S. ex. Rel. Greenfield*, 880 F.3d at 94–95 (quoting 42 U.S.C. § 1320a-7b(b)(2)(A)). The False Claims

Act imposes "liability on any person who '(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *U.S. ex rel. Greenfield*, 880 F.3d at 94. In addition, "[t]he Travel Act prohibits using interstate travel, mail, or facilities with intent to carry out 'any unlawful activity,' 18 U.S.C. § 1952(a)(3), or with intent to 'distribute the proceeds of any unlawful activity.'" *United States v. Ferriero*, 866 F.3d 107, 113 (3d Cir. 2017) (quoting 18 U.S.C. § 1952(a)(1)). The AICs accuse the Debtors of violating a multitude of state bribery laws. Without specifying which states, they claim that the "kickback" scheme to the doctors along with charitable foundation payments constituted bribes.

The AICs had to offer evidence that showed the Debtors' speaker programs specifically departed from the "common practice" and (1) violated federal and state law, in other words, committed a predicate act; (2) that the Debtors had the necessary scienter; and (3) the Debtors' speakers' programs were the but-for and proximate cause of their alleged injuries. I will address each requirement in turn.

a. *Explaining the Predicate Acts*

During the post-petition period, the Debtors paid over $1.7 million to physicians for at least 443 speaker events as part of their speakers' bureau program.[103] Like many other specialty pharmaceutical companies in the field, the Debtors host these speaker programs to educate healthcare professionals about specific drugs, in this case Acthar.[104]

Despite over 440 programs, the AICs could not point to a single example of a post-petition physician payment that qualified as a remuneration in exchange for prescribing a drug for which reimbursement under a federal healthcare program is available in violation of 42

[103] PTO at 19.
[104] 11-12-21 Transcript at 64–66; 11-12-21 Transcript at 142.

United States Code § 1320a–7b(b)(2). In their pre-trial brief, the AICs pointed to documents describing a particular physician, "Pulmonologist A" and his prescribing behavior,[105] but they did not question any witnesses at the trial about this physician or the documents.

The AICs also pointed to ongoing investigations into the Debtors' payments to healthcare providers by the U.S. Attorney's Offices for the Middle District of Florida and Eastern District of Pennsylvania, and the fact that the Debtors have not changed their policies in response to those investigations.[106] They also made vague references to "issues" with the Debtors' speaker programs and certain things that were flagged as violative of Debtors' policies but did not explain how such incidents would support a finding that the Debtors' violated the law. If anything, they support the conclusion that the Debtors' policies were effective by ensuring the incidents were brought to the attention of and resolved by the Debtors' compliance department.

Here, I conclude the AICs again did not meet their burden. The Debtors chose speakers who are experts in the relevant therapeutic areas or have sufficient experience prescribing Acthar to speak about the drug, and they paid fair market value to the speakers and prohibited conducting any type of "return on investment" analysis about the prescribing habits of physicians engaged as speakers.[107] In addition, they monitored their speaker programs closely to prevent abuse, and the compliance team used a third party to manage logistics, including planning events consistent with Debtors' policies; ensuring that speaker compensation is at fair market value; enforcing dozens of other rules related to the programs; and providing detailed real-time, quarterly, and yearly compliance reports.[108] Those reports indicated that the Debtors fully

[105] Claimants' Pre-Trial Brief ¶¶ 53–54.
[106] 11-17-21 Transcript at 156–160.
[107] 11-17-21 Transcript at 126, 127–129; 11-17-21 Transcript at 192–193; DX 052, September 2020 Promotional Speaker Program Policy, §§ 6.1.3, 6.2.3.2.
[108] 11-17-21 Transcript at 111–113.

complied with their policies and did not knowingly and willfully induce physicians to write more Acthar prescriptions.[109] The AICs failed to show any violation of federal or state law and therefore have not met the predicate act requirement under the RICO Act.

b. *Lacking the Specific Intent*

The AICs also had to prove the Debtors acted with specific intent that their speaker programs would induce their *speakers* to prescribe more Acthar.[110] Yet, they failed to offer any evidence that would support this conclusion. Throughout the post-petition period, the Debtors had a compliance program, and they consistently reevaluated its policies to update them regarding interactions with physicians to fit within the latest legal and regulatory guidance. There is simply nothing in the evidence that would support the conclusion that the Debtors "knowingly and willfully" tried to induce their speakers to prescribe more Acthar in violation of the law.

c. *The But-for and Proximate Cause of the Speaker Programs*

Finally, under the physician speaker programs theory, the AICs had to show that the speaker programs were the but-for and proximate cause of their alleged injuries. Notably, "mere correlation does not demonstrate causation" under RICO. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 92 (2d Cir. 2015). The AICs attempt to establish the required but for causation by showing that after the speaker program began, there was an increase in demand for Acthar.[111] This is insufficient.

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[109] See DX 073, Post-Petition Period Speaker Bureau Metrics; 11-17-21 Transcript at 136-39, 142.
[110] This is not to be confused with an intention on the part of the Debtors that the speaker programs would result in more Acthar prescriptions generally. It is not unlawful for a company to pay a single physician to educate a group of physicians about a drug with the intention that *all* physicians might then increase the number of prescriptions they write for the drug. It is, however, unlawful for a company to pay a single physician to act as a "speaker" at an educational program with the intention that the payment made to that physician will then induce *that* physician to write more prescriptions for the drug.
[111] 11-12-21 Transcript at 169–171.

To explain the correlation between the increased prescriptions and the ramp up of the speaker program, the Debtors' expert, Dr. Jena, testified that physicians who prescribe Acthar more frequently tend to be more familiar with it and the relevant therapeutic areas; therefore, they are more qualified to speak about it.[112] Despite that fact, 94% of physicians who wrote prescriptions for Acthar post-petition were not speakers during that period.[113]

Going further, Dr. Jena, based on his physician-level analysis, determined that there was no empirical evidence that Mallinckrodt's speaker payments caused more doctors or speakers to increase prescribing Acthar in the post-petition period or before.[114] In fact, physicians tended to prescribe slightly fewer vials of Acthar per month after receiving their first speaker payment.[115] Even one of the AICs' witnesses, Christopher Ragan, acknowledge that Humana could not establish "an inappropriate relationship" between Debtors and a physician through information on speaker fees and prescribing rates alone.[116] The AICs failed to address this correlation in their argument and could not provide any evidence showing how the Debtors' speaker programs were the but-for cause of their alleged injuries.

In addition to the but-for cause, the AICs had to show the Debtors' speaker programs were the proximate cause of their alleged injuries. "When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006). Therefore, even if the Debtors' speaker programs sought to illegally induce additional

[112] 11-17-21 Transcript at 192–193.
[113] DX 607, Jena Rep., ex. 5.
[114] DX 607, Jena Rep., ex. 8; 11-17-21 Tr. at 180–181.
[115] 11-17-21 Transcript at 189 –191.
[116] 11-12-21 Transcript at 66.

prescriptions, the AICs had to show that those RICO violations directly led to more physicians prescribing Acthar to the detriment of the AICs, and that the doctors did not act independently.

In this case, the AICs, again, failed to offer any evidence that any physicians prescribed Acthar against their better judgment. Dr. Jena credibly testified that all the AICs have strict prior authorization requirements for Acthar.[117] The AICs' witness, Mr. Ragan, also admitted he had no knowledge of "any instances of misconduct related to prescriber kickbacks from Acthar in the [post-petition] window."[118] Mr. Ragan further testified that the Humana never took any measure to stop covering Acthar prescriptions made by paid speakers despite having the information of which physicians participated in the Debtors' speaker programs and acknowledging the audit capabilities to address any concerns.[119] The AICs had the ability and leverage to prevent their own alleged injuries by stopping to cover Acthar prescriptions they believed to be fraudulently induced. They had opportunities to audit any provider they had concerns about. The AICs never utilized these abilities despite the power to do so. Therefore, I find the AICs' alleged injury was not caused by the Debtors' conduct. The AICs' physician payments theory of RICO violations must also fail.

IV. Additional State Law Claims

Like the antitrust claims based on state law, because the AICs did not present any evidence at trial regarding their additional state law claims, or brief them in their post-trial briefing, I find they have also been abandoned.

[117] In one example, Humana only authorized coverage of Acthar outside of infantile spasms only when steroids were contraindicated or when physicians supplied evidence that their patients could not tolerate them. DX 657, Jena Suppl. Rep. 4–5, 29–31; 11-17-21 Transcript at 174–175, 179–180, 197–198; DX 607, Jena Rep. at pgs. 41–42, 47–49; DX 657 Jena Suppl. Rep. at pgs. 4–5, 29–31.
[118] 11-12-21 Transcript at 65.
[119] 11-12-21 Transcript at 65, 73–74.

CONCLUSION

In conclusion, I find that the AICs have not met their burden with respect to any of their claims. For that reason, their Motion for an order allowing an administrative expense claim is DENIED and the Debtors' Objection to the AICs' administrative claims is SUSTAINED.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

The Motion is **DENIED**.

Dated: December 21, 2021

JOHN T. DORSEY, U.S.B.J.