

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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GLAXOSMITHKLINE LLC,	:	
Plaintiff,	:	
v.	:	CIVIL ACTION NO. 19-5321
BOEHRINGER INGELHEIM	:	
PHARMACEUTICALS, INC.,	:	
Defendant.	:	
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MEMORANDUM OPINION

Rufe, J.

September 3, 2020

Plaintiff GlaxoSmithKline LLC (“GSK”) seeks to preliminarily enjoin Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BI”) from making certain marketing claims based on alleged violations of the Lanham Act’s prohibition on false advertising¹ and Pennsylvania common law. BI opposes GSK’s request. After considering the parties’ briefings and after a hearing, for the following reasons, GSK’s motion will be granted in part and denied in part.

I. BACKGROUND

Chronic Obstructive Pulmonary Disease (“COPD”) is a lung disease that causes obstructed airflow from the lungs.² Millions of Americans have been diagnosed with COPD and it is the third-leading cause of death by disease in the United States.³ Although there is no cure for COPD, there are medications that help patients manage the symptoms of COPD, and the market for these medications is enormous. By 2026, the global COPD market size is anticipated to be valued at around \$24.3 billion.⁴

¹ 15 U.S.C. § 1125(a).

² Decl. of Jill Ohar [Doc. No. 28-5] at 5.

³ *See id.*

⁴ *Billion by 2026: Acumen Research and Consulting*, GlobeNewswire, February 19, 2019, <https://www.globenewswire.com/news-release/2019/02/19/1734121/0/en/Chronic-Obstructive-Pulmonary-Disease-Market-Size-Worth-Around-USD-24-3-Billion-by-2026-Acumen-Research-and-Consulting.html>.

Most COPD medications are administered by inhalers. There are three main types of inhalers.⁵ Metered Dose Inhalers (“MDIs”), which deliver medication through an aerosol spray, were the original type of COPD inhaler; the spray is released when the patient presses on the inhaler. However, because MDIs require patients to coordinate inhalation with the release of aerosol spray, they can be difficult to use for patients with coordination problems.⁶

In response to the difficulty that some patients have with activating MDIs, Dry Powder Inhalers (“DPIs”), which are handheld breath-actuated devices, were developed.⁷ In a DPI, the COPD medication is combined with dry inactive carrier particles so that, when a patient inhales through the DPI, the inhalation separates the medication from the carrier particles and delivers the medication to the lungs.⁸ In other words, while MDIs require the patient to coordinate pressing a button and breathing, DPIs are activated only by the patient’s breathing effort. GSK markets several medications for COPD which are administered through its DISKUS and ELLIPTA DPIs.⁹ BI also markets a DPI called the HANDIHALER.

Slow Mist Inhalers (“SMIs”) are the third type of inhaler. SMIs uses spring power to generate low velocity mist into the mouth. The mist generation is sustained for approximately 1.5 seconds and requires some coordination of inhalation and activation of the device, although less coordination than an MDI.¹⁰ There is only one SMI on the market in the United States—with the HANDIHALER DPI’s exclusivity set to expire, allowing generic versions, in 2015, BI launched

⁵ Smaldone Decl. [Doc. No. 36-6] at 2.

⁶ *See id.* at 2.

⁷ *Id.*

⁸ *See id.*

⁹ Decl. of Jill Ohar [Doc. No. 28-5] at 7.

¹⁰ *See id.* at 8.

its RESPIMAT SMI and it currently markets two of its COPD medications through its RESPIMAT device.

Upon launching its SMI, BI faced the problem of convincing physicians to begin prescribing its SMI instead of the various DPIs on the market. BI's solution was to focus on COPD patients' peak inspiratory flow ("PIF" or "PIFR") which is measured in liters per minute ("L/min"). In June 2018, BI launched its current marketing campaign and began distributing the COPD Paradox Aid.¹¹ The campaign's premise is that, for DPI users, a COPD patient's ability to separate the COPD medication from the dry powder carriers depends on that patient's ability to inhale with sufficient force.¹² According to BI's campaign, the need for forceful inhalation gives rise to the so-called COPD Paradox—although DPIs have an "optimal PIF" of 60 L/min many COPD patients have "suboptimal PIF" of less than 60 L/min. Because SMIs do not require forceful inhalation, BI's marketing materials represents that physicians should take PIF into account and prescribe its SMI for patients with low PIF. At its base, this case comes down to whether BI has scientific support for its various statements about PIF and DPIs.

GSK convened an internal team to assess BI's new marketing campaign. In September 2018, GSK sent a letter to BI demanding that it cease using the COPD Paradox Aid and any other materials containing similar claims that DPIs are unsuitable for patients with "suboptimal" PIF. BI responded in October 2018 and asserted that its claims were supported by several scientific studies. In November 2018, the parties again exchanged letters disputing whether BI's assertions in the marketing campaign had scientific support. In January 2019, BI provided GSK with an exemplar of its Revised COPD Paradox Aid. The changes were minor; for example, BI

¹¹ Detail aids, such as the COPD Paradox Aid, Revised COPD Paradox Aid, and Current Visual Aid, are a marketing tool used by pharmaceutical representatives and provided to healthcare providers.

¹² *Id.* at 9.

revised the claim that “[m]ore than half of COPD patients can have suboptimal peak inspiratory flow”¹³ to “[m]any patients can have suboptimal peak inspiratory flow.”¹⁴ In May 2019, GSK responded and complained that the Revised Aid still was not supported by scientific studies. In June 2019, BI retorted and argued that the disputed statements were supported by science. Nonetheless, BI explained that it would discontinue using one of the disputed graphics.¹⁵

Between BI’s final letter to GSK in June 2019 and the initiation of this case, BI retired the Revised COPD Paradox Aid. In its place, BI is now using the Current Visual Aid. On November 12, 2019, GSK filed its Complaint and a Motion for Preliminary Injunction asserting that BI’s marketing campaign violates the Lanham Act and Pennsylvania unfair competition law. On February 10, 2020, GSK filed its Amended Motion for Preliminary Injunction seeking to enjoin BI’s use of the Current Visual Aid along with hundreds of other promotional and training pieces which it asserts include unsupported claims. A hearing on the Amended Motion for Preliminary Injunction was held on March 10, 2020. Having considered the parties’ arguments in their papers and at the hearing, the Court will grant GSK’s motion in part.

II. LEGAL STANDARD

“[A]n injunction is ‘an extraordinary remedy, which should be granted only in limited circumstances.’”¹⁶ “The moving party must establish four factors to get a preliminary injunction: (1) the likelihood that the plaintiff will prevail on the merits at final hearing; (2) the extent to which the plaintiff is being irreparably harmed by the conduct complained of; (3) the extent to which the defendant will suffer irreparable harm if the preliminary injunction is issued; and (4)

¹³ COPD Paradox Aid [Doc. No. 38-14] at 2.

¹⁴ Revised COPD Paradox Aid [Doc. No. 38-15] at 3.

¹⁵ Ex. I, Kilgard Decl. [Doc. No. 40-5].

¹⁶ *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)).

that the public interest weighs in favor of granting the injunction.”¹⁷ “[A] movant for preliminary equitable relief must meet the threshold for the first two ‘most critical’ factors: it must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief.”¹⁸ “If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief.”¹⁹

III. DISCUSSION

A. Likelihood of Success on the Merits

To prevail on a claim for false advertising under the Lanham Act, a plaintiff must prove: “1) that the defendant has made false or misleading statements as to his own product [or another’s]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.”²⁰

As to the “false or misleading statements” requirement,” a “plaintiff can prevail . . . if it proves that the advertisement ‘is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers.’”²¹ “A ‘literally false’ message may be either explicit or

¹⁷ *Greater Philadelphia Chamber of Commerce v. City of Philadelphia*, 949 F.3d 116, 133 (3d Cir. 2020) (cleaned up).

¹⁸ *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017).

¹⁹ *Id.*

²⁰ *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011) (quoting *Warner–Lambert v. Breathasure*, 204 F.3d 87, 91–92 (3d Cir. 2000)).

²¹ *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014) (quoting *Novartis*, 290 F.3d at 586).

‘conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.’²² However, “only an unambiguous message can be literally false.”²³ “Proof of literal falsity relieves the plaintiff of its burden to prove actual consumer deception.”²⁴

Where, as here, “an advertising claim of favorable fact either expressly or impliedly asserts that the fact is testor study-validated, the fact of the validation becomes an integral and critical part of the claim. Such a claim may therefore be proven literally false by showing only that the test asserted to validate it did not in fact do so.”²⁵ In other words, because BI’s advertisements “represent[] that tests or studies prove its product superior,” to prove falsity, GSK has the burden of either showing that “the tests were not sufficiently reliable to permit a conclusion that the product is superior” or “that the tests did not establish the proposition for which they were cited.”²⁶ In evaluating GSK’s claim, the Court “consider[s] all relevant circumstances, including the state of the testing art, the existence and feasibility of superior

²² *Novartis*, 290 F.3d at 586–87 (quoting *Clorox Co. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 35 (1st Cir. 2000)).

²³ *Id.* at 587.

²⁴ *Groupe SEB USA*, 774 F.3d at 198 (citing *Novartis*, 290 F.3d at 586).

²⁵ *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 435 (4th Cir. 1997); *see also Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 952 (3d Cir. 1993) (Roth, J., dissenting) (citations omitted) (“As the majority has implicitly recognized, a different burden of proof faces a Lanham Act plaintiff who challenges an ‘establishment’ advertising claim that states that ‘tests prove’ the asserted proposition than faces a plaintiff who challenges a ‘non-establishment’ claim that makes no statement that ‘tests prove’ the asserted proposition.”); *BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1090 (7th Cir. 1994); *Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514–15 (8th Cir. 1996) (collecting cases); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1309 n.6 (11th Cir. 2010) (citations omitted); *CareDx, Inc. v. Natera, Inc.*, No. 19-662, 2019 WL 7037799, at *8 (D. Del. Dec. 20, 2019), *report and recommendation adopted*, No. 19-662, 2020 WL 401773 (D. Del. Jan. 24, 2020); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 467 (D.N.J. 2009).

²⁶ *Castrol*, 977 F.2d at 63 (citations omitted); *see also Rhone-Poulenc*, 93 F.3d at 514.

procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests.”²⁷

If the court deems an ad to be literally true, in order to prove that the ad is misleading, “the movant—even at the preliminary injunction stage—must present evidence of deception.”²⁸ “Because the concern is ‘the message that is conveyed to consumers,’ to fall under the statute’s coverage of deceptive statements, a message that is not literally false must be proved to have misled the public by showing actual confusion on the part of consumers: ‘Public reaction is the measure of a commercial’s impact.’”²⁹ “The plaintiff must persuade the court that the persons to whom the advertisement is addressed would find that the message received left a false impression about the product.”³⁰

1. The scientific background for BI’s marketing materials

Dr. Jill Ohar, BI’s expert, submitted a declaration to the Court in which she reviewed several peer-reviewed studies and concluded that “[t]he optimal PIF with respect to most DPIs, including GSK’s DISKUS and ELLIPTA, is widely considered to be >60 L/min. Patients who cannot achieve the optimal PIF against the resistance of their prescribed device may benefit from an alternative inhaler device” and that “[c]onsideration of PIF by both patients and physicians is particularly important because, as both the evidence and my own practice show, low PIF is

²⁷ *Procter & Gamble Co. v. Chesebrough-Pond’s Inc.*, 747 F.2d 114, 119 (2d Cir. 1984).

²⁸ *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1247 (11th Cir. 2002).

²⁹ *Alpha Pro Tech, Inc. v. VWR Int’l, LLC*, No. 12-1615, 2017 WL 3671264, at *13 (E.D. Pa. Aug. 23, 2017) (quoting *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.*, 19 F.3d 125, 129–30 (3d Cir. 1994)).

³⁰ *U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia*, 898 F.2d 914, 922 (3d Cir. 1990) (cleaned up).

common in some segments of the COPD population.”³¹ The Court will begin by considering whether the cited studies support these conclusions.³²

First, the tests cited by Dr. Ohar support BI’s proposition that a PIF of greater than 60 L/min is considered optimal. For example, the *Dhand* study stated that “[o]ne of the key factors affecting optimal drug delivery via an inhaler is whether the patient can generate a sufficient or appropriate PIF rate . . . most DPIs require a minimum flow rate of 30 L/min, and a flow rate of >60 L/min to function optimally.”³³

Second, the medical literature substantiates the notion that low PIF is common among COPD patients. For example, the *Loh* study found that, out of the 123 patients, 52% had a PIF below 60 L/min.³⁴ In fact, Dr. Gerald Smaldone, GSK’s expert, concedes that one of the studies

³¹ Decl. of Jill Ohar [Doc. No. 28-5] at 19.

³² The Court notes that, except for one study, the studies cited by BI are all in peer-reviewed journals and no reliability concerns have been identified.

³³ Rajiv Dhand, *et al.*, *Considerations for Optimal Inhaler Device Selection in Chronic Obstructive Pulmonary Disease*, 85 *Cleveland Clinic J. Med.* S19, S23 (Feb. 2018) (copy attached as Ex. A, Decl. of Jill Ohar [Doc. No. 28-5]). GSK asserts that “[t]here is no clinical or otherwise established definition of ‘forceful inhalation’ or of ‘optimal’ or ‘suboptimal’ PIF, but BI defines ‘suboptimal PIF’ as a PIF below 60 liters per minute (L/min).” Mem. of Law. in Supp. of GSK’s Mot. for Prelim. Inj. [Doc. No. 38] at 6. However, the studies cited by BI clearly establish the proposition that a PIF below 60 L/min is suboptimal. See Chee H. Loh, *et al.*, *Suboptimal Inspiratory Flow Rates Are Associated with Chronic Obstructive Pulmonary Disease and All-Cause Readmissions*, 14 *Annals Am. Thoracic Soc’y* 1305, 1306 (Aug. 2017) (copy attached as Ex. C, Decl. of Jill Ohar [Doc. No. 28-5]); see also Donald A. Mahler, *et al.*, *Prevalence and COPD Phenotype for a Suboptimal Peak Inspiratory Flow Rate against the Simulated Resistance of the Diskus Dry Powder Inhaler*, 26 *J. Aerosol Med. Pulmonary Drug Delivery* 174, 174 (Nov. 2013) (copy attached as Ex. D, Decl. of Jill Ohar [Doc. No. 28-5]) (“A peak inspiratory flow rate (PIFR) of ≤ 60 L/min against the internal resistance (resist) of a DPI is considered optimal.”); W. Janssens, *et al.*, *Inspiratory flow rates at different levels of resistance in elderly COPD patients*, 31 *Eur. Respir. J.* 78, 79 (2008) (copy attached as Ex. E, Decl. of Jill Ohar [Doc. No. 28-5]).

³⁴ Loh, *supra* note 33, at 1307; see also Gulshan Sharma, *et al.*, *Prevalence of Low Peak Inspiratory Flow Rate at Discharge in Patients Hospitalized for COPD Exacerbation*, 4 *J. COPD Found* 217 (2017) (copy attached as Ex. G, Decl. of Jill Ohar [Doc. No. 28-5]) (finding that 31.7% of patients had a PIF below 60 L/min); Sohini Ghosh, *et al.*, *Prevalence and factors associated with suboptimal peak inspiratory flow rate in COPD*, 14 *Int’l J. Chron. Obstruct. Pulmon. Dis.* 585, 589 (2019) (copy attached as Ex. F, Decl. of Jill Ohar [Doc. No. 28-5]) (“Discordance, defined as suboptimal PIFR against any prescribed inhaler, was observed in 40% of COPD patients without the commonly reported factors associated with low PIFR such as poor effort, older age, small stature, malnutrition, and air trapping.”).

cited by BI shows that “a high number of the DPI users, who were not acutely ill with respiratory complaints, had a PIF below 60 L/min.”³⁵

Third, consideration of PIF is important because, as Dr. Ohar states, even though “a correlation between suboptimal PIF and clinical outcomes has not been established, emerging evidence is beginning to demonstrate” a correlation.³⁶ The *Loh* study concluded that “[p]atients with [suboptimal PIF] had higher rates of 90-day readmission for COPD, days to all-cause readmissions, and days to COPD readmission.”³⁷ Moreover, in the study’s multivariate model, “[suboptimal PIF] was the only variable that predicted days to COPD readmission.”³⁸

Because BI has identified reliable studies that support its marketing campaign, GSK must prove that “these [studies] did not establish the proposition for which they were cited.”³⁹ Dr. Smaldone asserts that BI’s marketing materials contain false statements because “[d]espite the focus of [BI’s] papers, there is no clinical evidence establishing a link between PIF and clinical efficacy of COPD medication.”⁴⁰ Furthermore, according to Dr. Smaldone, “[o]nly a clinical trial can determine whether or not a patient receives an adequate dose of medication,” and because “[s]ome studies have shown that a lung deposition of as little as 10% of an emitted dose of COPD medication can effectively treat a patient . . . any statement that patients with suboptimal

³⁵ Supp. Decl. of Gerald Smaldone [Doc. No. 38-9] at 4. The Court notes that the study that Dr. Smaldone was referring to has not yet been peer-reviewed. However, Dr. Smaldone did not challenge the study’s finding that a significant number of COPD patients had a PIF below 60 L/min and, in any event, BI has relied on several other peer-reviewed studies that support this claim.

³⁶ Ohar Supp. Decl. [Doc. No. 41-68] at 16.

³⁷ *Loh*, *supra* note 33, at 1307.

³⁸ *Id.* at 1308–09. Another study concluded that patients with suboptimal PIF who received medication via a nebulizer had “substantial improvements in lung function” compared to similar patients who received similar medication via a DPI. Donald A. Mahler, *et al.*, *Nebulized Versus Dry Powder Long-Acting Muscarinic Antagonist Bronchodilators in Patients With COPD and Suboptimal Peak Inspiratory Flow Rate*, 6 *Journal of the COPD Foundation* 321, 328 (Sept. 2019) [Doc. No. 41-72].

³⁹ *Castrol*, 977 F.2d at 63 (citation omitted).

⁴⁰ Smaldone Decl. [Doc. No. 36-6] at 4.

PIF who use a DPI may not achieve successful drug delivery or may be at risk for compromised treatment is not supported by clinical evidence or scientific literature.”⁴¹ However, BI does not dispute this point; it has consistently acknowledged in both its marketing materials and in this litigation that “[a] correlation between suboptimal PIF and clinical outcomes has not been established.”⁴² Therefore, in sum, marketing by BI is not literally false if it represents that: 1) the optimal PIF to operate a DPI is >60 L/min; 2) many COPD patients have a PIF that is suboptimal; and 3) studies suggest that some patients with suboptimal PIF may benefit from a non-DPI inhaler. On the other hand, any marketing that represents that a correlation between suboptimal PIF and clinical outcomes has been established, *i.e.*, that patients with suboptimal PIF do not receive an adequate dose of medication, crosses the line.

2. *Whether BI is making any false statements*

GSK identifies 12 statements—from four marketing materials—that BI makes in its marketing campaign documents that it asserts are literally false.

i. Current Visual Aid

GSK argues that the cover page of the Current Visual Aid “conveys the central, false theme of BI’s campaign”—that a particular PIF is “required to use DPIs” even though the cited studies do not support such a claim.⁴³ GSK specifically challenges the statement that “[m]any patients with COPD cannot forcefully inhale because they live with damaged lungs . . . yet . . . [a]ll dry powder inhalers (DPIs) require patients to forcefully inhale to optimally activate. Now,

⁴¹ Supp. Decl. of Gerald Smaldone [Doc. No. 38-9] at 2.

⁴² Current Visual Aid [Doc. No. 38-10] at 2, 7; *see also* Ohar Supp. Decl. [Doc. No. 41-68] at 16.

⁴³ Mem. of Law. in Supp. of GSK’s Mot. for Prelim. Inj. [Doc. No. 38] at 21–22.

there is new evidence from the first large-scale, real-world study of peak inspiratory flow (PIF).”⁴⁴

This statement is not literally false. Footnotes at the end of these sentences reference the *Loh* and the *Ghosh* studies, which support the propositions that, although DPIs are optimally activated at a PIF of >60 L/min, many COPD patients are unable to achieve that PIF.⁴⁵ GSK argues that there is no clinical definition of “forcefully inhale” but, based on the referenced studies, it is clear that “forcefully inhale” in this context means achieve a PIF that is deemed optimal, *i.e.* >60 L/min.⁴⁶ Moreover, on multiple pages, the Aid properly draws the line at what the cited studies support and prominently displays the disclaimer that “[a] correlation between suboptimal PIF and clinical outcomes has not been established.”⁴⁷ Considering that the Aid is targeted to physicians, its statements are supported by scientific studies, the studies are referenced for physicians to review, and the Aid specifically explained the limits of what it could

⁴⁴ Current Visual Aid [Doc. No. 38-10] at 1.

⁴⁵ The footnotes also reference the study that has not yet been peer-reviewed but that Dr. Smaldone conceded shows that “a high number of the DPI users, who were not acutely ill with respiratory complaints, had a PIF below 60 L/min.” Supp. Decl. of Gerald Smaldone [Doc. No. 38-9] at 4. Although this study has not been peer-reviewed, other studies cited by BI, including the *Loh* study, establish that many COPD patients have a PIF below 60 L/min.

⁴⁶ GSK also argues that the FDA does not require a minimum PIF to use a DPI. Mem. of Law. in Supp. of GSK’s Mot. for Prelim. Inj. [Doc. No. 38] at 22. However, to successfully defend against GSK’s Lanham Act suit, BI only needs to provide reliable scientific support for its marketing. The cited studies support BI’s claim that emerging evidence shows that PIF is an important consideration for DPI users. Moreover, draft guidance from the FDA has stated that the label on DPIs should include a statement “that the amount of drug delivered to the lungs will depend on patient factors, such as inspiratory flow and PIF through the delivery system, which may vary for asthma, COPD, and other patient populations.” See U.S. Food & Drug Admin., Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Products – Quality Considerations, 34–35 (April 2018), *available at* <https://www.fda.gov/downloads/drugs/guidances/ucm070573.pdf>. “Although guidance documents do not legally bind FDA, they represent the agency’s current thinking.” 21 C.F.R. § 10.115(d)(3).

⁴⁷ Current Visual Aid [Doc. No. 38-10] at 2, 7. GSK argues that this disclaimer is ineffective because the Second Circuit has held that where a “deception is caused by a clear and unambiguous false representation . . . and, because of this, the addition of a qualifying phrase denying the truth of that representation would lead to a confusing contradiction in terms, no remedy short of complete excision of the trade name will suffice.” *Cont’l Wax Corp. v. F. T. C.*, 330 F.2d 475, 479–480 (2d Cir. 1964) (citing *F.T.C. v. Algoma Lumber Co.*, 291 U.S. 67, 81–82 (1934)). However, the Aid did not make a clear and unambiguous false representation; as explained, the Aid properly stated what the cited studies support.

accurately claim, the Court concludes that the Current Visual Aid does not contain a literally false statement.

ii. Suboptimal Inhaler Box

BI's marketing campaign also includes an advertisement in the form of a box. The box is labeled "Dry Powder Inhaler" and includes a disclaimer stating "WARNING: Suboptimal Inhaler Included."⁴⁸ Inside the box is a plastic figurine of a COPD patient, as well as a BI marketing pamphlet.⁴⁹ GSK argues that this advertisement constitutes a "false statement that DPIs are suboptimal compared to any other COPD inhalers and that they might not work for certain patients."⁵⁰ BI argues that the advertisement is a "play on words."⁵¹ According to BI, "[t]he 'suboptimal inhaler included' language printed on the lid of the Box refers to the COPD patient—not a DPI."⁵²

Although the outside of the box alone potentially conveys the false message that DPIs are suboptimal,⁵³ the advertisement as a whole conveys the message supported by BI's studies that many COPD patients are suboptimal inhalers and is not literally false. Upon opening the box and seeing the figurine, and as there is no DPI in the box, physicians likely will understand the intended message. As BI sales representatives were instructed to "[p]ut the box in the customer's hands," it is unlikely that physicians will fail to open the box.⁵⁴ Therefore, GSK has not shown a likelihood of success on the merits of this claim.

⁴⁸ Dry Powder Inhaler Box [Doc. No. 38-38].

⁴⁹ *See id.*

⁵⁰ Mem. of Law. in Supp. of GSK's Mot. for Prelim. Inj. [Doc. No. 38] at 23.

⁵¹ Defendant's Mem. of Law in Opp. to Pl.'s Am. Mot. for Prelim. Inj. [Doc. No. 41] at 29.

⁵² *Id.*

⁵³ As Dr. Ohar explains, "there is no perfect inhaler for all patients. Each device has its own unique strengths and weaknesses." Decl. of Jill Ohar [Doc. No. 28-5] at 4.

⁵⁴ Field Communication [Doc. No. 38-50] at 1.

iii. Respiratory Learning System

GSK also challenges three statements in a BI internal training document titled Respiratory Learning System. First, GSK argues that the statement that “[t]he efficacy of aerosol deposition in the lungs is dependent upon the peak inspiratory flow rate (PIFR) of the patient” is false.⁵⁵ BI asserts that the *Clark* study supports this statement because that study found that “[p]owder distribution generally improves as pressure drops and inhaled flow rates increase because the increased energy supply disperses the powder more effectively. . . . In most scenarios . . . lung dose increases with increasing flow rate.”⁵⁶ However, as GSK argues, BI has not established that patients with a low PIF will not receive an adequate amount of COPD medication. Although BI has support for the proposition that PIF is correlated with an improvement in powder distribution, BI has not established the amount of powder that a COPD patient on a DPI must inhale in order for the medication to properly work. According to Dr. Smaldone, “studies have shown that a lung deposition of as little as 10% of an emitted dose of COPD medication can effectively treat a patient.”⁵⁷ Thus, while the *Clark* study supports BI’s representation that patients with a low PIF will receive less COPD medication from a DPI, BI has not established that they will not receive *enough* medication. Therefore, GSK has shown a likelihood of success on the merits of its claim that the challenged statement is false.

⁵⁵ Respiratory Learning System [Doc. No. 38-41] at 9.

⁵⁶ Andrew Clark, *et al.*, *The Confusing World of Dry Powder Inhalers: It Is All About Inspiratory Pressures, Not Inspiratory Flow Rates*, 33 *Journal of Aerosol Medicine and Pulmonary Drug Delivery* 1, 3 (Jan. 2020) [Doc. No. 41-69].

⁵⁷ Supp. Decl. of Gerald Smaldone [Doc. No. 38-9] at 2. The Respiratory Learning System itself includes the disclaimer that “[t]he relationship between deposition and distribution of inhaled drugs in the lungs and clinical efficacy and safety is not known” on virtually every page. Respiratory Learning System [Doc. No. 38-41] at 3–19.

Second, GSK challenges the statement that “DPIs may not be appropriate for some COPD patients based on the minimum required PIFR.”⁵⁸ As explained above, however, BI has support for the proposition that many COPD patients have a suboptimal PIF for using DPIs and that these patients may benefit from using alternative inhalers. BI’s statements do not represent that a correlation between suboptimal PIF and clinical outcomes has been established; rather, they accurately state that, as peer-reviewed scientific studies have concluded, PIF is a relevant consideration. Therefore, this statement is not false.

Third, GSK challenges the statement that “[t]he efficacy of aerosol deposition [for SMIs] in the lungs is independent of the patient’s inspiratory flow rate.”⁵⁹ BI argues that the *Clark* study supports this statement. The *Clark* study explained that most DPIs are “passive, in the sense that they rely on the patient’s inspiratory effort to fluidize and disperse the drug powder sufficiently well to enter and deposit in the lungs.”⁶⁰ The study concludes that “[a]ssessing patients’ ability to generate a minimum pressure drop of 1 kPa across any resistance in the range of typical DPI device resistances should be an effective way of deciding if they are candidates for DPI use.”⁶¹ By contrast, the study explains that a SMI is an “active inhaler” which can be used as an alternative to a DPI when the COPD patient is unable to generate the minimum pressure.⁶² The *Clark* study supports the proposition that the efficacy of aerosol deposition for SMIs in the lungs is independent of the patient’s inspiratory flow rate, so this statement is not false.

⁵⁸ Respiratory Learning System [Doc. No. 38-41] at 9.

⁵⁹ *Id.*

⁶⁰ Clark, *supra* note 56, at 6.

⁶¹ *Id.* at 9.

⁶² *Id.*

iv. Field Communication

BI's Field Communication is a training tool for its sales representatives that has the goal of helping BI's sales representatives prompt physicians to "consider if their prescribing behavior is truly optimal for patients who struggle to breathe and gain their agreement that peak inspiratory flow and inhaler choice matter when treating COPD."⁶³ "The objective of this training tool is to help" BI sales representatives address physicians' "current beliefs around the dry powder inhalers . . . by referring to and leaving behind the peer-reviewed clinical trials and review articles upon which [BI's marketing campaign] is based: *Ghosh, Loh, and Sharma*."⁶⁴ GSK argues that seven statements in this document are literally false.

First, the Field Communication instructs BI's sales representatives to leave a copy of the *Sharma* study with physicians which, according to the Field Communication:

[P]rovides a different perspective on the role of suboptimal peak inspiratory flow and its clinical implications. The difference in readmission rates between the optimal and suboptimal groups were not statistically different. However, *Sharma* is the first study to identify the prevalence of suboptimal peak inspiratory flow following discharge and asserts that inspiratory effort should be assessed to determine if prescribing a DPI is appropriate. As a result, further study is necessary regarding the relationship between suboptimal peak inspiratory flow and clinical outcomes.⁶⁵

This statement is true. The *Sharma* study states that "PIFR can be used to assess a patient's ability to generate adequate inspiratory flow rate, and thus can be used to guide COPD treatment choices. DPIs have internal resistance and patients with diminished PIFR may not be able to inhale medications using a DPI effectively into the lower respiratory tract . . . [f]uture

⁶³ Field Communication [Doc. No. 38-50] at 4.

⁶⁴ *Id.*

⁶⁵ *Id.* at 6.

research is needed to understand the optimal treatment of patients with low PIFR compared with patients with normal PIFR.”⁶⁶

Second, GSK challenges BI’s instruction to its sales representatives to inquire “Doctor, how do you currently assess your patients’ ability to use their DPIs optimally?”⁶⁷ As explained above, however, BI has support for the proposition there is an optimal PIF for using DPIs which is unattainable for many COPD patients.

Third, the Field Communication states that “[t]he *Ghosh* study provides a list of recommended minimal and optimal peak inspiratory flow rates for DPIs currently in the market. DPIs such as Diskus, Ellipta, and Neohaler require a PIF ranging from 50 – 60 L/min in order to optimally activate.”⁶⁸ This statement is not false because the *Ghosh* study recommends defining optimal PIF as >60 L/min for both the DISKUS and ELLIPTA inhalers.⁶⁹

Fourth, GSK argues that the Field Communication’s statement that the “*Loh, Sharma, and Ghosh . . . studies point to emerging evidence that peak inspiratory flow matters*” is false.⁷⁰ However, as explained above, these studies do indicate that PIF is relevant for physicians considering which inhaler to prescribe.

Fifth, GSK also argues that the Field Statement contains the false statement that “*Loh* goes on to state that serious clinical consequences may be associated with patients who can’t forcefully inhale in order to optimally activate (or who suffer from suboptimal peak inspiratory

⁶⁶ Sharma, *supra* note 34, at 222–23.

⁶⁷ Field Communication [Doc. No. 38-50] at 6.

⁶⁸ *Id.*

⁶⁹ Sohini Ghosh, *et. al.*, *Peak Inspiratory Rate in Chronic Obstructive Pulmonary Disease: Implications for Dry Powder Inhalers*, 6 J. Aerosol Med. Pulmonary Drug Delivery 381, 382–83 (2017) [Doc. No. 41-70].

⁷⁰ Field Communication [Doc. No. 38-50] at 7.

flow) via a DPI.”⁷¹ This statement is not false because the *Loh* study concluded that “[p]atients who do not achieve optimal PIFs are at risk of readmission.”⁷²

Sixth, the Field Communication instructs sales representatives to inform physicians that “if patients’ inspiratory ability is already compromised, then prescribing a DPI may be creating an unnecessary obstacle in their treatment.”⁷³ Again, however, BI has support for its claim that COPD patients with a suboptimal PIF may benefit from a non-DPI inhaler.

Finally, GSK challenges the instruction to BI’s sales representatives to ask physicians “[w]ith so many DPIs requiring forceful inhalation to optimally activate and with so many patients with damaged lungs . . . ‘why should patients with COPD work so hard to optimally activate their inhaler?’”⁷⁴ GSK argues that this statement is false because “there is no evidence that COPD patients are working harder to use DPIs than other types of COPD inhalers” and “many patients prefer DPIs and find DPIs easier to use than other COPD inhalers.”⁷⁵ However, this statement is not literally false because BI has demonstrated that many DPIs have an optimal PIF of >60 L/min and that many COPD patients have suboptimal PIF. Therefore, in order to optimally activate their inhalers, these patients would need to work harder.

In addition to BI’s cited studies supporting the statements made in the Field Communication, the Field Communication specifically instructs sales representatives to inform physicians that “further study is necessary regarding the relationship between suboptimal peak inspiratory flow and clinical outcomes”⁷⁶ and sales representatives were instructed to leave

⁷¹ *Id.*

⁷² *Loh*, *supra* note 33, at 1311.

⁷³ Field Communication [Doc. No. 38-50] at 9.

⁷⁴ *Id.* at 10.

⁷⁵ Supp. Decl. of Gerald Smaldone [Doc. No. 38-9] at 6.

⁷⁶ Field Communication [Doc. No. 38-50] at 6.

copies of the relevant studies with the physicians and to disclose the limitations in these studies to “provide the appropriate context around the data.”⁷⁷ Therefore, the Court concludes that none of the challenged statements in the Field Communication are literally false.

3. *Whether BI is making any misleading statements*

As explained above, a party seeking to preliminarily enjoin misleading statements “must present evidence of deception.”⁷⁸ Actual deception or tendency to deceive can be proven “with a properly conducted consumer survey.”⁷⁹ “The evidentiary value of a survey depends on its underlying objectivity as determined through many factors, such as ‘whether [the survey] is properly “filtered” to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive.’”⁸⁰ “[S]urvey evidence demonstrating that 15% of the respondents were misled . . . is sufficient to establish the ‘actual deception or at least a tendency to deceive a substantial portion of the intended audience,’ necessary to establish a Lanham Act claim for false or misleading advertising.”⁸¹

GSK provides a chart listing 90 statements which it alleges are misleading.⁸² But GSK only provides evidence of deception for the challenged statement in the Current Visual Aid, which GSK argues is misleading even if it is not literally false.⁸³ In 2019, GSK commissioned

⁷⁷ *See id.* at 4, 7.

⁷⁸ *Johnson & Johnson*, 299 F.3d at 1247.

⁷⁹ *Pernod*, 653 F.3d at 248 (citing *Novartis*, 290 F.3d at 586, 588–90).

⁸⁰ *Novartis*, 290 F.3d at 591 (quoting *Johnson & Johnson–Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 300 (2d Cir. 1992)).

⁸¹ *Id.* (quoting *Rhone-Poulenc*, 19 F.3d at 129).

⁸² Tab 19, Mem. of Law in Supp. of GSK’s Mot. for Prelim. Inj. [Doc. No. 38-19].

⁸³ The Court notes that consumer surveys are not always necessary to establish evidence of deception; sometimes, the totality of the evidence submitted by the movant is enough to establish a likelihood of success on the merits even without a survey. *See Eli Lilly & Co. v. Arla Foods, Inc.*, 893 F.3d 375, 382 (7th Cir. 2018). Here, however, GSK has not come close to meeting its burden. Besides the individual ads themselves, GSK has submitted nothing beyond

Dr. Susan McDonald, the President and CEO of NAXION, a marketing research and consulting organization, to design and conduct a survey to determine whether BI's now-expired COPD Paradox Aid misleads physicians. In response to the open-ended Questions 1 and 2—which asked 331 physicians: “What message or messages does this material communicate to you?—Dr. McDonald coded 51% of the respondents’ answers as stating that BI’s messaging conveyed that “COPD patients with suboptimal PIF don’t get sufficient benefit from their inhalers.”⁸⁴ In response to Question 3—which asked: “What, if anything, does material convey or suggest about use of certain dry DPIs for COPD patients with suboptimal peak inspiratory flow (PIF)?”—34% of the responses were coded as stating that “[e]fficacy of DPI medications may be compromised/insufficient for some patients with low/reduced PIF.”⁸⁵ Therefore, the survey results show that, even though BI concedes that no studies have established a correlation between PIF and clinical outcomes, a substantial number of physicians were deceived into believing that DPIs do not work for COPD patients with suboptimal PIF.⁸⁶

BI argues that Dr. McDonald’s survey is irrelevant because she surveyed physicians about the now-expired COPD Paradox Aid, not the Current Visual Aid. However, the COPD Paradox Aid is substantially similar to the Current Visual Aid. As BI’s Director of Respiratory

its own say-so to prove deception. Considering the complexity of the science, the sophistication of the targeted physicians, and BI’s efforts to toe the line and only state what its cited studies support, the Court cannot conclude that BI’s statements are misleading based only on the marketing materials themselves. *See Johnson & Johnson*, 299 F.3d at 1247 (“While ‘full-blown consumer surveys or market research are not an absolute prerequisite,’ the moving party must provide ‘expert testimony or other evidence.’”) (quoting *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1183 (8th Cir. 1998)).

⁸⁴ McDonald Survey Results [Doc. No. 36-27] at 10.

⁸⁵ *Id.* at 12.

⁸⁶ BI quibbles with several of the responses that Dr. McDonald coded as “COPD patients with suboptimal PIF don’t get sufficient benefit from their inhalers” and included in the 51%. Defendant’s Mem. of Law in Opp. to Pl.’s Am. Mot. for Prelim. Inj. [Doc. No. 41] at 33–34 & n.23, n.24. However, even after excising the few responses that BI challenges, the survey results still show that well over 15% of physicians were misled into believing that “COPD patients with suboptimal PIF don’t get sufficient benefit from their inhalers.”

Marketing stated in a memo sent to the sales team, “[d]on’t worry, the new assets are very similar to the old assets in terms of the overall story content and message flow. You will see immediately that the changes are relatively minor . . . [w]e are very confident that these new assets will help you continue to tell the core story”⁸⁷ Moreover, Dr. McDonald, the only marketing expert whose opinion has been presented to the Court, concluded that “[t]he updated editions are so little changed that they qualify as mere distinctions without a difference.”⁸⁸ After a careful review of the two Aids, and Dr. McDonald’s analysis, the Court credits Dr.

McDonald’s conclusion that:

The historic and ongoing BI campaign draws a clear through-line from the notion that “suboptimal PIF can equate to reduced efficacy” by reassembling the same message elements in a continuous thread. There are explicit repeats and there are persistent patterns. One would not need to survey each and every iteration to reach the conclusion that the message was communicated in prior pieces, and that it continues to be communicated now.⁸⁹

Dr. McDonald’s survey was comprehensive and compelling. BI cannot dodge the legal consequences of that survey by making superficial tweaks to its marketing materials, turning Lanham Act litigation into a never-ending shell game. Because GSK has presented evidence that the Current Visual Aid is misleading physicians into believing that patients with suboptimal PIF

⁸⁷ Tab 16, Mem. of Law in Supp. of GSK’s Mot. for Prelim. Inj. [Doc. No. 38-16] at 2.

⁸⁸ McDonald Decl. [Doc. No. 38-13] at 24.

⁸⁹ *Id.* at 25. For example, the statement in the COPD Paradox Aid that “MORE THAN HALF of COPD patients can have suboptimal peak inspiratory flow (PIF)” evolved to “MANY COPD patients can have suboptimal peak inspiratory flow (PIF)” in the Revised COPD Paradox Aid and “suboptimal PIF was found in more than half of patient assessments in a subgroup analysis” in the Current Visual Aid. Similarly, the COPD Paradox Aid stated that “[y]our patients live with damaged lungs and many cannot forcefully inhale . . . yet . . . [m]any COPD inhalers may require your patients to forcefully inhale,” the Revised COPD Paradox Aid stated that “[m]any COPD patients cannot forcefully inhale, yet many COPD inhalers require them to do so in order to optimally activate,” and the Current Visual Aid stated that “[m]any patients with COPD cannot forcefully inhale because they live with damaged lungs . . . yet . . . [a]ll dry powder inhalers (DPIs) require patients to forcefully inhale to optimally activate.” Likewise, the message about hospital readmissions evolved from “[p]atients with suboptimal PIF may have a higher risk of COPD hospital readmission” in both the COPD Paradox Aid and the Revised COPD Paradox Aid to “on readmission, suboptimal PIF was found in more than half of the assessments in the subgroup analysis.”

will not receive sufficient benefit from DPIs, GSK has shown a likelihood of success on its claim that the Current Visual Aid is violating the Lanham Act.

4. *Materiality, Interstate Commerce & Likelihood of Injury*

BI does not appear to dispute the materiality, interstate commerce, and likelihood of injury elements of the Lanham Act claim, and GSK has demonstrated a likelihood of success on the merits as to these elements. First, a deception is material if “it is likely to influence purchasing decisions,” and informing physicians that certain COPD treatments might not be effective for certain patients is likely to influence their prescribing decisions.⁹⁰ Second, both GSK and BI distribute their inhalers through the channels of interstate commerce.⁹¹ Third, as discussed below, GSK is suffering irreparable harm from BI’s marketing campaign.

In sum, GSK has demonstrated a likelihood of success on the merits of its claim that parts of BI’s marketing campaign—specifically, the Current Visual Aid and the statement in the Respiratory Learning Systems document that “[t]he efficacy of aerosol deposition in the lungs is dependent upon peak inspiratory flow”—violate the Lanham Act.

B. GSK’s Irreparable Harm

“In order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial. The preliminary injunction must be the *only* way of protecting the plaintiff from harm.”⁹² “The requisite feared injury or harm must be irreparable — not merely serious or substantial, and it must be of a peculiar nature, so that compensation in money cannot atone for it.”⁹³ “Thus, a litigant seeking

⁹⁰ *Dentsply Int’l, Inc. v. Great White, Inc.*, 132 F. Supp. 2d 310, 325 (M.D. Pa. 2000).

⁹¹ *U.S. Healthcare*, 898 F.2d at 922.

⁹² *Checker Cab of Philadelphia Inc. v. Uber Techs., Inc.*, 643 F. App’x 229, 232 (3d Cir. 2016) (citation omitted).

⁹³ *Kamdem-Ouaffo v. Task Mgmt. Inc.*, 792 F. App’x 218, 221 (3d Cir. 2019) (quoting *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91–92 (3d Cir. 1992)).

injunctive relief must ‘articulate and adduce proof of actual or imminent harm which cannot otherwise be compensated by money damages . . . to sustain its substantial burden of showing irreparable harm.’”⁹⁴ Harm to reputation or goodwill can constitute irreparable injury because it is “virtually impossible to quantify in terms of monetary damages.”⁹⁵ The preliminary injunction standard requires the plaintiff to make a clear showing that “it is more likely than not to suffer irreparable harm in the absence of preliminary relief.”⁹⁶

BI argues that GSK cannot meet its burden because “GSK’s claim of irreparable harm is belied by both GSK’s lack of diligence in seeking immediate injunctive relief, and by the undisputed data demonstrating that GSK has suffered no competitive harm.”⁹⁷ First, because GSK waited 17 months after learning about BI’s alleged false statements to demand a preliminary injunction, BI relies on the Third Circuit’s unpublished decision in *Lanin v. Borough of Tenafly* for the proposition that “preliminary injunctions are generally granted under the theory that there is an urgent need for speedy action to protect the plaintiffs’ rights Delay in seeking enforcement of those rights . . . tends to indicate at least a reduced need for such drastic, speedy action.”⁹⁸

In *Lanin*, however, the Third Circuit also explained that “delay may be excused where the party seeking a preliminary injunction delays only in the reasonable belief that negotiations may resolve the dispute.”⁹⁹ Here, GSK learned about BI’s marketing campaign in the summer of

⁹⁴ *Id.* (quoting *Frank’s GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102–03 (3d Cir. 1988)).

⁹⁵ See *Groupe SEB USA*, 774 F.3d at 205 n.8 (citation omitted); see also *id.* at 204 (citing *S & R Corp. v. Jiffy Lube Int’l, Inc.*, 968 F.2d 371, 378 (3d Cir. 1992)).

⁹⁶ *Reilly*, 858 F.3d at 179.

⁹⁷ Defendant’s Mem. of Law in Opp. to Pl.’s Am. Mot. for Prelim. Inj. [Doc. No. 41] at 24.

⁹⁸ *Id.* (quoting 515 F. App’x 114, 117–18 (3d Cir. 2013)).

⁹⁹ *Lanin*, 515 F. App’x at 118 (citing *Atari Corp. v. Sega of America, Inc.*, 869 F.Supp. 783, 790 (N.D.Cal. 1994)).

2018. Over the summer, GSK convened an internal team to assess BI's campaign. In September 2018, GSK sent a letter to BI complaining about BI's communications concerning PIF. GSK and BI exchanged a number of letters about the campaign through June 2019. Significantly, in response to GSK's complaints, BI revised some of its marketing materials. In November 2019, Dr. McDonald submitted her expert report presenting the findings from the nationwide survey she conducted. That same month, GSK initiated this action and sought injunctive relief. GSK's conduct, "which entailed an initial resort to a consensual resolution of the controversy" and then waiting to obtain evidence necessary to support its claim, "did not constitute unreasonable delay."¹⁰⁰

Second, because it is undisputed that GSK's market share has not suffered since BI's marketing campaign began, BI asserts that GSK cannot make a clear showing that it is suffering irreparable harm. The irreparable harm that GSK faces is to its long-term goodwill and reputation, however. As Dr. McDonald explained in her declaration, "[p]harmaceutical marketing is given structure by campaigns that unfold over a period of years to advance a particular strategy . . . [i]t takes time to make a case."¹⁰¹ Here, because "virtually none of the physicians in practice today have been trained in their medical education to rely on PIF (or to think about PIF at all), it will take time, repetition, and iteration to prime the marketplace for behavior change."¹⁰²

¹⁰⁰ *Glaxosmithkline Consumer Healthcare, L.P. v. Merix Pharm. Corp.*, No. 05-898, 2005 WL 2230318, at *11 (D.N.J. Sept. 13, 2005), *aff'd*, 197 F. App'x 120 (3d Cir. 2006) (citing *Millenium Import Co. v. Sidney Frank Importing Co.*, 2004 WL 1447915 (D. Minn. June 11, 2004)).

¹⁰¹ McDonald Decl. [Doc. No. 38-13] at 7–8.

¹⁰² *Id.* at 20.

Dr. McDonald further explained that “time is not on GSK’s side.”¹⁰³ Even though clinical studies have not proven that PIF is correlated to clinical outcomes, “[w]ith repeated exposure over time [to BI’s marketing campaign], innuendo and suggestion are likely to take firm shape in physicians’ minds” and “physicians can often be persuaded to act on speculation so long as they don’t feel they are putting patients at risk.”¹⁰⁴ This is especially so in the COPD context because COPD is a “leading cause of death, but there have been no dramatic advances in treatment therapy for years.”¹⁰⁵ Therefore, according to Dr. McDonald, “physicians can be nudged to accept an interesting idea as relevant” even though no conclusive evidence exists to show the impact of the idea on patients.¹⁰⁶ In other words, “[t]he whiff of smoke that keeps on blowing can easily lead physicians to infer that there is a real fire.”¹⁰⁷

Moreover, Dr. McDonald’s survey—which showed that 34% of respondents understood BI’s marketing to indicate that the “[e]fficacy of DPI medications may be compromised/insufficient for some patients with low/reduced PIF”¹⁰⁸—demonstrates that even though GSK has not yet begun to lose market share, BI’s marketing campaign is damaging the reputation and goodwill of GSK’s DPIs. GSK sales representatives have also reported that multiple hospitals are now “testing PIF and if below 60, they are switching patients off of ELLIPTA products.”¹⁰⁹ Dr. McDonald explained that “[t]he equity drained away through brand reputation risk may never be recovered. It will be hard for physicians to ‘unhear’ these ideas

¹⁰³ *Id.* at 21.

¹⁰⁴ *Id.* at 22.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 22–23.

¹⁰⁸ McDonald Survey Results [Doc. No. 36-27] at 12.

¹⁰⁹ Tab 46, GSK’s Am. Mot. Prelim. Inj. [Doc. No. 36-24] at 1; Tab 44, GSK’s Am. Mot. Prelim. Inj. at 21 [Doc. No. 36-24] at 2.

once heard because the burden of definitively disproving (or proving) them is too onerous for any company with a stake in this market to entertain.”¹¹⁰

GSK need not wait until its market share begins to suffer and it is too late to obtain injunctive relief; the Court credits Dr. McDonald’s opinion that the continuation of BI’s marketing campaign is likely to fundamentally alter the existing paradigm for treating COPD in ways that irreparably harm GSK’s reputation and goodwill. Therefore, the false and misleading advertising claims, the competitive relationship between GSK and BI over COPD medication, and Dr. McDonald’s expert opinion all support a conclusion that GSK is more likely than not suffering irreparable harm to its reputation and goodwill.¹¹¹

C. Public Interest and BI’s Harm

“[W]here the plaintiff has demonstrated a likelihood of success on the merits, the public interest leans even more toward granting the injunction.”¹¹² Moreover, “[t]here is a strong public interest in the prevention of misleading advertisements.”¹¹³ BI argues, however, that the health and safety of COPD patients is a public interest that militates in favor of denying GSK’s motion because GSK’s preliminary injunction “would deprive COPD patients with suboptimal PIF—an indisputably substantial portion of patients who suffer from COPD—of important health information concerning different types of inhalers available by prescription.”¹¹⁴

¹¹⁰ McDonald Decl. [Doc. No. 38-13] at 23–24.

¹¹¹ See *Groupe SEB USA*, 774 F.3d at 204–05; *GlaxoSmithKline Consumer Healthcare, L.P. v. Merix Pharm. Corp.*, 197 F. App’x 120, 123 (3d Cir. 2006).

¹¹² *Novartis*, 290 F.3d at 597.

¹¹³ *Id.* (quoting *American Home Prods. Corp. v. Johnson & Johnson*, 654 F.Supp. 568, 590 (S.D.N.Y. 1987)); see also *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 730 (3d Cir. 2004) (“Indeed, neither the district court nor the parties even mentions the most basic public interest at stake in all Lanham Act cases: the interest in prevention of confusion, particularly as it affects the public interest in truth and accuracy.”).

¹¹⁴ Defendant’s Mem. of Law in Opp. to Pl.’s Am. Mot. for Prelim. Inj. [Doc. No. 41] at 35.

Although BI is correct that the public has an interest in the health and safety of COPD patients, that interest is not detrimentally affected here.¹¹⁵ The injunction that the Court will issue only enjoins BI from making false and misleading statements not supported by scientific studies, and therefore the health and safety of COPD patients is more likely protected, not placed at risk by the Court’s injunction.¹¹⁶ BI can still advertise its SMI and make truthful statements about PIF and DPIs, and physicians can make educated decisions based on those statements.¹¹⁷ Therefore, because the only interest at stake is the prevention of misleading advertisements, the public interest weighs in favor of granting the preliminary injunction.

D. Bond

Federal Rule of Civil Procedure 65(c) provides that “[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.”¹¹⁸ “[T]he injunction bond ‘provides a fund to use to compensate incorrectly enjoined defendants.’”¹¹⁹ Although neither party has mentioned bond, or suggested an appropriate amount, the Third Circuit has held that “[t]he District Court must set a bond even where the parties have neglected to raise the issue.”¹²⁰ “[W]hen setting the amount of

¹¹⁵ See *Kos*, 369 F.3d at 730–31.

¹¹⁶ BI also argues that the First Amendment is implicated by GSK’s proposed injunction. However, the Court is only enjoining BI from making false and misleading statements. See *Novartis*, 290 F.3d at 597–599.

¹¹⁷ For the same reasons, BI will not face irreparable harm.

¹¹⁸ Fed. R. Civ. P. 65(c).

¹¹⁹ *Sprint Commc’ns Co. L.P. v. CAT Commc’ns Int’l, Inc.*, 335 F.3d 235, 240 (3d Cir. 2003) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 804 (3d Cir. 1989)).

¹²⁰ *Tilden Recreational Vehicles, Inc. v. Belair*, 786 F. App’x 335, 343 (3d Cir. 2019) (citing *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 426 (3d Cir. 2010)); see also Note, *Recovery for Wrongful Interlocutory Injunctions Under Rule 65(c)*, 99 HARV. L. REV. 828, 830 (1986) (explaining that Rule 65(c) “puts the determination of the bond amount in the district court’s discretion and does not oblige the court to justify that determination with any supporting evidence”) (citation omitted). “There is an ‘extremely narrow exception’ allowing for waiver of the bond requirement only ‘when complying with the preliminary injunction raises no risk of monetary loss to the defendant,’ and the District Court ‘make[s] specific findings’ in support of that conclusion.” *Tilden*, 786 F. App’x at

security, district courts should err on the high side” because the movant still has to prove its loss to receive the bond while “[a]n error in the other direction produces irreparable injury, because the damages for an erroneous preliminary injunction cannot exceed the amount of the bond.”¹²¹ The Court will therefore set bond at \$5,000,000. The amount of the bond may be modified upon the filing of a properly-supported motion by either party.

IV. CONCLUSION

For the foregoing reasons, GSK’s Amended Motion for Preliminary Injunction will be **GRANTED in part** and **DENIED in part** as defined in the Court’s separate Order.

343 (quoting *Zambelli*, 592 F.3d at 426). That exception is inapplicable here because BI is at risk of losing substantial sums of money if its marketing campaign designed to capture parts of the billion-dollar COPD market is disrupted. Moreover, the Third Circuit has “never excused a District Court from requiring a bond where an injunction prevents commercial, money-making activities.” *Zambelli*, 592 F.3d at 426.

¹²¹ *Habitat Educ. Ctr. v. U.S. Forest Serv.*, 607 F.3d 453, 456 (7th Cir. 2010) (citation omitted); *see also Pella Prod., Inc. v. Pella Corp.*, No. 18-1030, 2018 WL 2734820, at *15 (M.D. Pa. June 7, 2018). There is “an exception for a case in which the bond is both higher than necessary and beyond the plaintiff’s financial capacity, and thus inflicts irreparable harm without justification.” *Habitat Educ. Ctr.*, 607 F.3d at 456 (citing *Friends of the Earth, Inc. v. Brinegar*, 518 F.2d 322 (9th Cir. 1975); *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1126 (9th Cir. 2005)).

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<hr/>	:	
GLAXOSMITHKLINE LLC,	:	
Plaintiff,	:	
v.	:	CIVIL ACTION NO. 19-5321
BOEHRINGER INGELHEIM	:	
PHARMACEUTICALS, INC.,	:	
Defendant.	:	
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ORDER

AND NOW, this 3rd day of September 2020, upon consideration of Plaintiff’s Amended Motion for Preliminary Injunction [Doc. No. 36], the responses thereto, and all related filings, after a hearing held on March 10, 2020, and for the reasons stated in the accompanying Memorandum Opinion, it is hereby **ORDERED** that the Amended Motion is **GRANTED in part** and **DENIED in part** as follows:

- 1) BI shall **CEASE AND DESIST** from conveying in promotional, training, and/or educational materials the following messages or creating the false or misleading impression that the following messages are true (the “Prohibited Claims”):
 - a. Peak inspiratory flow (PIF) has any effect upon the efficacy of drugs used to treat Chronic Obstructive Pulmonary Disease (COPD);
 - b. The deposition of a therapeutic or adequate dose of medication in the lungs is dependent upon the peak inspiratory flow rate (PIFR) of the patient;
 - c. A meaningful number of patients are unable to activate dry powder inhalers (DPIs); and
 - d. DPIs are “suboptimal inhalers.”
- 2) Given their use of the Prohibited Claims, BI shall **CEASE AND DESIST** using the Current Visual Aid and the Respiratory Learning System training document.

- 3) BI shall prominently display – in a font no smaller than the majority of the type, on the pertinent page – the following disclaimer on all promotional materials for COPD medications that reference PIF: “A relationship between PIF and the efficacy of COPD medications has not been established.”
- 4) BI shall promptly re-train all of its sales representatives to ensure that they no longer make any of the Prohibited Claims.
- 5) In all other respects, GSK’s Amended Motion is **DENIED**.
- 6) Bond is set at \$5,000,000.

It is so **ORDERED**.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFÉ, J.