UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR LEAVE TO AMEND MASTER LONG FORM AND SHORT FORM COMPLAINTS TO ADD CLAIM FOR PUNITIVE DAMAGES**

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Plaintiffs submit this Memorandum in Support of their Motion for Leave to Amend their Master Long Form and Short Form Complaints to Add a Claim for Punitive Damages. The facts presented below provide *prima facie* evidence that 3M Company and Arizant Healthcare, Inc. ("Defendants" or "the company") deliberately disregarded patient safety.

LEGAL STANDARD

A transferee court overseeing multidistrict litigation may grant a motion to amend to add a claim for punitive damages. *See, e.g.*, *In re Levaquin Prod. Liab. Litig.*, MDL No. 08-1943, 2014 WL 11395078, at *6 (D. Minn. 2014). At this stage, the Court need not "determine the extent to which, if at all, any other state's law relative to punitive damages would apply to any particular plaintiff's claims." *See id*. When considering a motion to amend to assert a claim for punitive damages, the Court should look to the procedural requirements outlined in Minnesota statutes. *In re Levaquin Prod. Liab. Litig.*, MDL No.

08-1943 (JRT), 2010 WL 7852346, at *6–10 (D. Minn. 2010). As Chief Judge Tunheim explained in the Levaquin MDL, "Minnesota Statute § 549.20 is a remedial provision to which a conflict of law analysis does not apply." *Id*. at *10. Even if the statute were not remedial in nature, "Minnesota's [conflict of law analysis] would dictate the application of Minnesota law to the issue of punitive damages in this [multidistrict litigation]." *See id*.

Minnesota law permits an award of punitive damages upon a showing that the defendant deliberately disregarded the rights or safety of others. *See* Minn. Stat. § 549.20, subd. 1. This occurs where, as here, the defendant "has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others" and "deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others" or "deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others." *See id*.

On a motion to amend the complaint to assert a punitive damages claim, however, the standard is much lower. *See*, *e.g*., *id*. at *6. Plaintiffs "need not demonstrate an entitlement to punitive damages *per se*, but only an entitlement to allege such damages." *Berczyk v*. *Emerson Tool Co*., 291 F. Supp. 2d 1004, 1008 (D. Minn. 2003). Plaintiffs need only offer *prima facie* evidence, which, if unrebutted, could support a finding of deliberate disregard for the rights or safety of others. *See In re Levaquin*, 2010 WL 7852346, at *6; *see also Tousignant v*. *St*. *Louis Cnty*., 615 N.W.2d 53, 59 (Minn. 2000) ("[A] *prima facie* case simply means one that prevails in the absence of evidence invalidating it.") (internal citations omitted). Accordingly, in determining whether to grant Plaintiffs' motion, "the

Court makes no credibility rulings, and does not consider any challenge, by cross-examination or otherwise, to [Plaintiffs'] proof." *Berczyk*, 291 F. Supp. 2d at 1008 n.3.

ARGUMENT

Like here, plaintiffs in the Levaquin MDL moved to amend their complaint to add a claim for punitive damages. In granting the motion, Chief Judge Tunheim explained that if the plaintiffs' evidence was fully believed and accepted as true, a jury could reasonably infer that the defendants had: (1) knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause injury; (2) manipulated scientific studies to produce commercially favorable results; (3) failed to adequately warn the plaintiffs and their doctors of the dangers of Levaquin, despite knowing the particular risks of using the drug; and (4) affirmatively misrepresented Levaquin's safety profile to the public through their marketing campaign and other tactics. *See In re Levaquin*, 2010 WL 7852346, at *10.

Judge Noel likewise granted a motion to add claims for punitive damages in the Mirapex MDL. In doing so, Judge Noel relied on the plaintiffs' *prima facie* evidence that the defendants had: (1) failed to properly research the dangers of the product and to warn patients about the same; (2) publicly denied there was a causal link between the product and those dangers; (3) failed to report important information about the product to the FDA; (4) delayed conducting a study on the product; and (5) suppressed additional research on the product. *In re Mirapex Prod. Liab. Litig.*, 2007 WL 9636345, at *6–9 (D. Minn. 2007).

The conduct at issue in this MDL is similar in every respect. Through this motion, Plaintiffs offer *prima facie* evidence regarding each of the following deliberate actions:

- Defendants designed and marketed the Bair Hugger without performing any safety validation with respect to the known risk of airborne contamination.

- Defendants not only secretly cut the efficiency of the Bair Hugger filter without validating the safety of the new filtration level, but they hid this change from the FDA, healthcare providers, and the public.

- Defendants knew the inadequate filter would result in increased particles passing through the filter, causing internal contamination of the Bair Hugger.

- Defendants' product engineers repeatedly developed feasible design changes that would have reduced, if not eliminated, the risk of internal contamination, but all of these changes were rejected by management.

- Defendants willfully disregarded medical research regarding the potential for the Bair Hugger to harm patients through disruption of the surgical field.

- Defendants were aware of the weaknesses and limitations of the research they used to support the Bair Hugger but never warned the public of the same.

- Defendants engineered and manipulated scientific research to produce commercially favorable results.

- Defendants prevented, discredited, and suppressed scientific inquiry regarding the potential for the Bair Hugger to increase the risk of orthopedic infections.

- Defendants affirmatively misrepresented the safety of the Bair Hugger and failed to warn customers, healthcare providers, and the public of those risks.

Viewed collectively or independently, this conduct shows that Defendants knew the Bair Hugger posed a serious safety risk to orthopedic patients but deliberately acted with intentional disregard to the high probability of injury to patients. *See* Minn. Stat. § 549.20.

Indeed, among other patient safety risks, Defendants knew the Bair Hugger could disrupt the sterile surgical field and mobilize pathogens to the surgical site. They also knew that the device could harbor dangerous pathogens, adding bioburden to the sterile surgical environment. Though Defendants knew that either one of those mechanisms could cause deep joint infections in orthopedic patients, they ignored, suppressed, and distorted the evidence. *See In re Mirapex*, 2007 WL 9636345, at *1, *14 (granting plaintiffs' motion to add claim for punitive damages because defendants "ignored" evidence of safety risks and "attempted to suppress" the evidence rather than warning patients of "possible side effect").

1. Defendants Failed to Validate the Safety of the Bair Hugger.

When the company first developed the Bair Hugger in 1987, it submitted a 510(k) notification to the FDA identifying a substantially equivalent predicate device. [redacted] Since that time, each and every model of the Bair Hugger, including the Bair Hugger 505, 750, and 775, has been intended for intraoperative use even though the original predicate devices were not designed to be used in that manner.[3]

[1] Exhibit 1 to the Declaration of Genevieve M. Zimmerman (hereinafter "Exhibit 1"), 1987-09-14 510(k) Notification Letter – 3MBH00047858–67.
[2] *Id*. at 3MBH00047859.
[3] *See*, *e.g*., Exhibit 2, 1996-01-10 510(k) Summary of Safety & Effectiveness – 3MBH00047382–83.

Plaintiffs' expert Dr. Yadin David, the Chairman of the FDA's Medical Device Good Manufacturing Practices Advisory Committee, explained in his report that unlike Class III devices, which require a "rigorous approval process," the primary responsibility for safety validation for Class II devices like the Bair Hugger lies with the manufacturer.[4] While "the FDA relies on the assurances of the manufacturer that appropriate performance testing and validation has occurred,"[5] [redacted] **despite the well-established link between particles and infections.[7]** [redacted].[10]

[4] Exhibit A, Report of Dr. Yadin David at 17.
[5] *Id*. at 18.
[6] Exhibit 3, Deposition of Gary Maharaj at 97:3–15 (emphasis added).
[7] *See* Exhibit B, Report of Dr. William Jarvis at 14–15; *see also* Exhibit 4, Proceedings of the International Consensus Meeting On Periprosthetic Joint Infections at 115–116.
[8] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 49:13–18; 51:5–16.
[9] Exhibit 6, Deposition of Teri Woodwick-Sides at 57:20-59:10.
[10] Exhibit 7, Deposition of David Westlin at 117:18–24.

The same held true with respect to the Model 750. [redacted]

[redacted]

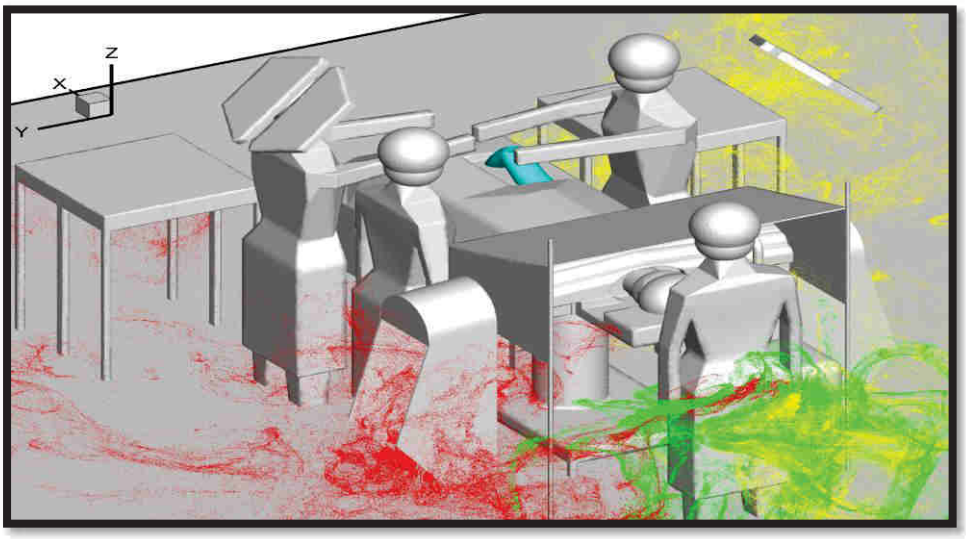
[11] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 87:16-89:20.
[12] Exhibit 8, Deposition of Karl Zgoda at 42:22-43:5 (emphasis added).
[13] *Id*. at 39:20.
[14] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 90:22-91:3 (emphasis added).

While such testing was never performed by Defendants before marketing the device, it was recently performed by Plaintiffs' expert Mr. Michael Buck, an expert in air quality investigations who has worked in the Department of Environmental Health and Safety at the University of Minnesota for over two decades.[15] This test involved measuring particles produced from both new and used Bair Hugger units using a laser optical particle counter in a laboratory clean room.[16] As stated in Mr. Buck's report, "[t]he evaluations showed clearly the Bair Huggers – through all operational modes – demonstrated increased production of particles from internal and/or external sources."[17] Mr. Buck thus concludes that both used and new Bair Hugger units cause "an increase in the number of particles in the operating room, and in particular, in close proximity to the surgical site."[18] This creates an alarming patient safety issue because increased particles increase the risk of infection.[19]

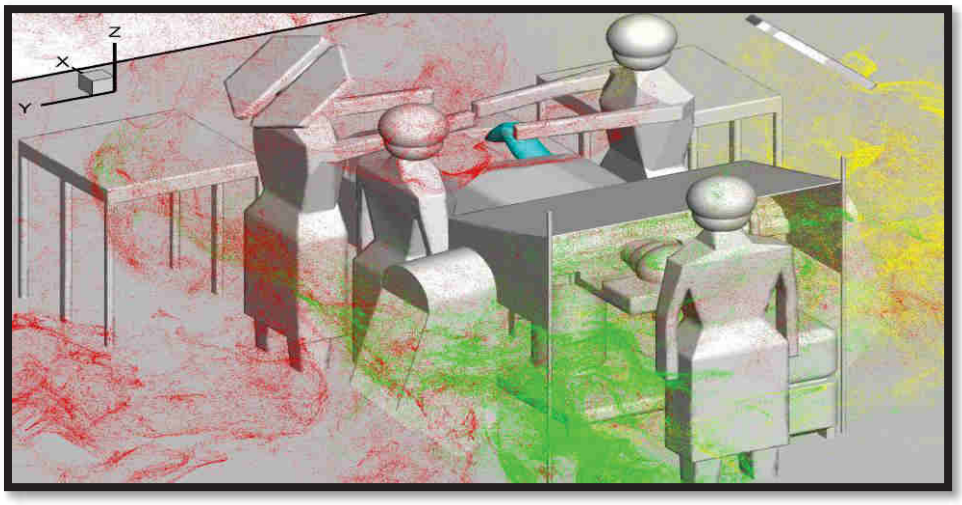
Moreover, Plaintiffs' expert Dr. Said Elghobashi recently performed computational fluid dynamic modeling at the University of California, Irvine to create a "large-eddy simulation (LES) of the interaction between the ventilation air flow and forced hot air from a [Bair Hugger] blower."[20] The results indisputably show that "hot air from the blower and the resultant thermal plumes are capable of lifting the particles and transporting them to

[15] Exhibit C, Report of Mr. Michael Buck at 3.
[16] *Id*. at 7–16.
[17] *Id*. at 17.
[18] *Id*.
[19] *See* Exhibit B, Report of Dr. William Jarvis at 14–15; *see also* Exhibit E, Report of Dr. Jonathan Samet at 14–17.
[20] Exhibit D, Report of Dr. Said Elghobashi at 2.

the side tables, above the operating table, and [to] the surgical site."[21] Imaging from the computational simulation further shows particles entering the area of the surgical incision:



(Scatter plot of particles with Bair Hugger turned off. Exhibit D at 50, Fig. 24(a)).



(Scatter plot of particles with Bair Hugger turned on. Exhibit D at 50, Fig.24(b)).

If Defendants had performed proper validation testing prior to marketing the Bair Hugger, they would have found the same patient safety issue. After all, Defendants had

[21] *Id*. at 62 (lines 825–27).

[redacted][23]

This evidence supports Plaintiffs' "contention that, had reasonable research or testing been performed, the risk could have been foreseen." *Smith v. Louisville Ladder Co.*, 237 F.3d 515, 532 (5th Cir. 2001) (internal citation omitted). It also shows, as discussed in Dr. Yadin David's expert report, that Defendants deliberately disregarded patient safety by failing their "obligation under the regulations to perform adequate safety validation prior to marketing the device."[24] *See In re Mirapex*, 2007 WL 9636345, at *10 (concluding that defendant's failure to study side effects "establish[ed] a *prima facie* case that [it] acted with disregard for the high probability of injury to the rights and safety of others"). While this single irresponsible act could alone justify an award of punitive damages, it was just the start of nearly 20 years of willful and reckless conduct that put millions of patients at risk.

[22] *See* Exhibit 9, Photograph of Warning Label on Inside Cover of Bair Hugger Model 200.
[23] Exhibit 8, Deposition of Karl Zgoda at 205:11–18 (emphasis added).
[24] Exhibit A, Report of Dr. Yadin David at 44.

2. Defendants Secretly Reduced the Filtration Efficiency of the Device.

[redacted]

[25] *See* Exhibit 5, Deposition of Corporate Representative Al Van Duren at 49:2–18; *see also* Exhibit B, Report of Dr. Williams Jarvis at 14–15.
[26] *See* Exhibit 5, Deposition of Corporate Representative Al Van Duren at 25:10–13; *see also* Exhibit B, Report of Dr. Williams Jarvis at 14–15.
[27] Exhibit 10, 2008-08-04 Internal Email – 3MBH00022373.
[28] Exhibit 2, 1996-01-10 Summary of Safety & Effectiveness – 3MBH00047382.

[redacted][31]

Dr. David's report explains how Defendants concealed this change from the FDA:

[redacted]

[29] Exhibit A, Report of Dr. Yadin David at 21.
[30] *Id*.
[31] *Id*. at 22 (citing 3MBH00022367).
[32] *Id*. (emphasis added).
[33] *Id*. at 21.
[34] Exhibit 11, 2000-05-01 Internal Design Notes – 3MBH01735812.

[redacted]

[redacted][36] Dr. David discusses the regulatory implications of this discussion:

> A letter-to-file is created when a manufacturer makes a non-significant change to an existing legally-marketed product and creates internally documented justifications showing the reasons for change and test results that demonstrate why the change does not impact the safety level or the efficacy of the product. . . . When a manufacturer makes a change, it must use one of two forms of compliance with this FDA requirement: (1) letter-to-file when the change is not significant, or (2) submit to the FDA special 510(k) submission or PMA supplement when the change is significant. In either form the manufacturer must demonstrate that the change did not impact safety or efficacy of the device.

[redacted]

[redacted]

[redacted]

[35] Exhibit 12, 2003-08-26 Internal Email – 3MBH01031246.
[36] *Id*.
[37] Exhibit A, Report of Dr. Yadin David at 23–24 (emphasis added) (citations omitted).
[38] *Id*. at 25.

[redacted] Dr. David explains how Defendants disregarded their duties when making this critical design change:

> When a manufacturer makes a change in the device's components, the hazard analysis needs to be updated. According to the FDA regulation 21 CFR 820.39(i), this requires that "Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation." The objective of the program – hazard mitigation and control – is maintained for the purpose of preventing production of defective devices that can endanger consumers and preventing hazardous devices from reaching the market. [redacted]

Failing to inform the FDA of these material changes, while further hiding them from healthcare providers and the public, "constitutes a *prima facie* case that [Defendants] acted with deliberate disregard for the risks or safety of others." *In re Mirapex*, 2007 WL

[39] *Id*. (emphasis added).
[40] Exhibit 13, 2010-11-17 FDA Establishment Inspection Report – 3MBH00048072.
[41] Exhibit A, Report of Dr. Yadin David at 25.
[42] *See* Exhibit 14, 2012-03-16 Internal Email – 3MBH00132832; *see also* Exhibit 15, 2013-10-07 Internal Email – 3MBH00126140.
[43] Exhibit 14, 2012-03-16 Internal Email – 3MBH00132832.

9636345, at *10; *see also id*. at *12–13 (allowing plaintiff to plead punitive damages claim in part because defendant omitted important information in correspondence with FDA); *In re Levaquin*, 2010 WL 785234, at *10 (failure to inform public of risks and misrepresenting safety profile of drug was *prima facie* evidence of deliberate disregard for public safety).

3. Defendants Know the Device is Contaminated with Bacteria But Rejected Numerous Proposals to Solve this Patient Safety Problem.

After silently slashing the filtration efficiency of the Bair Hugger, the company received reports from a variety of sources indicating the presence of dangerous bacteria inside the device—[redacted].[44] For example, in a study published in INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY entitled *Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment*, the authors evaluated medical equipment involved in an outbreak of dangerous infections.[45] They found contaminated particles in the interior of a Bair Hugger containing pathogens that were isolated to the same strain of bacteria responsible for the outbreak.[46]

[redacted]

[44] Exhibit 16, Deposition of Dr. Daniel Sessler at 64:21–23.
[45] Exhibit 17, 2004-11-01 Bernard Study – 3MBH00018429.
[46] *Id*.
[47] Exhibit 18, 2009-03-04 Internal Email – 3MBH00024633 [redacted] Exhibit 19, 2009-08-02 Internal Email – 3MBH00024678 [redacted].).
[48] Exhibit 20, 2006-11-01 Customer Letter – 3MBH00008941.

[redacted]

[49] *Id*.
[50] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[51] *See* Exhibit 8, Deposition of Teri Woodwick-Sides at 127:19.
[52] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[53] *Id*. at 3MBH00022629 (emphasis added).
[54] *Id*.
[55] *Id*. at 3MBH00022642–47.
[56] Exhibit 22, Internal Document re Filtration Topics – 3MBH00022877.

[redacted]

[redacted][62]

[redacted]

[57] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH 00022634.
[58] *Id*.
[59] Exhibit 20, 2006-11-01 Customer Letter – 3MBH00008941.
[60] Exhibit 23, 2009-06-04 Ion Armor Testing Report – 3MBH00025006.
[61] *Id*. (emphasis added).
[62] *Id*.

[redacted]

[redacted][65]

[redacted]

[redacted]

[63] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[64] *Id*.
[65] *Id*.
[66] Exhibit 24, 2013-08-24 Internal Memorandum – 3MBH01617179–80.
[67] *Id*.

[68] Exhibit 15, 2013-10-07 Internal Email – 3MBH00126140.
[69] *Id*.
[70] Exhibit 25, Deposition of Mark Scott at 205:13–14.
[71] Exhibit 26, 2013-08-26 Internal Email – 3MBH00542396.
[72] *Id*.
[73] *Id*.
[74] Exhibit 27, 2014-03-05 Blower Hose Ideation PowerPoint – 3MBH00630074.

[redacted]

[redacted]:

[redacted]

[75] Exhibit A, Report of Dr. Yadin David at 36.
[76] Exhibit 27, 2014-03-05 Blower Hose Ideation PowerPoint – 3MBH00630074.
[77] *Id*.

[redacted]

[redacted]

[redacted]:

[redacted]

[78]

[redacted]

[redacted]:

[redacted]

[79]

[78] *Id.*
[79] *Id.*

[redacted]

[redacted]

[redacted]

[redacted]:

[redacted]

[81]

[80] *Id.*
[81] *Id.*

[redacted] Since internal contamination of the Bair Hugger can cause contamination of the sterile surgical field,[85] which in turn increases the risk of deep joint infection in orthopedic patients,[86] Defendants' decision not [redacted] "constitute[s] a *prima facie* case that [they] acted with deliberate or conscious disregard for the rights or safety of others." *In re Mirapex*, 2007 WL 9636345, at *9; *see In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 572 (8th Cir. 2009) (pattern of inaction in addressing safety risk constituted reckless disregard of safety).

[82] Exhibit A, Report of Dr. Yadin David at 38.
[83] Exhibit 28, 2015-07-16 Internal Email – 3MBH01922062.
[84] *Id*.
[85] *See* Exhibit B, Report of Dr. William Jarvis at 10–13.
[86] *See* Exhibit E, Report of Dr. Jonathan Samet at 13–17.

4. Defendants Know of Scientific Literature Finding Infection Risks.

Over the last ten years, Defendants have encountered numerous scientific studies identifying patient safety risks from use of the Bair Hugger in orthopedic surgeries. Any single one of the studies identified below would have caused a reasonably prudent manufacturer to seriously investigate the issue, particularly among orthopedic patients.[87] *See, e.g.*, *In re Levaquin*, 2010 WL 7852346, at *10 ("From [plaintiffs'] evidence . . . a jury could reasonable infer that defendants . . . had knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause tendon injuries, particularly in seniors using corticosteroids[.]"). [redacted].[88] *See In re Mirapex*, 2007 WL 9636345, at *9 (granting motion to add claim for punitive damages in part because "numerous reports of compulsive gambling from the clinical trials should have induced [defendants] to research the issue further and to warn patients about the possible side effects"). Defendants therefore deliberately disregarded patient safety. *See In re Prempro*, 586 F.3d at 572 (concluding that pattern of undermining "adverse" studies demonstrated a reckless disregard of patient safety sufficient to allege punitive damages).

For example, as early as 2009, [redacted] a scientific study published in ORTHOPEDIC REVIEWS entitled *Forced air warming: a source of airborne contamination*

[87] *See, e.g.*, Exhibit B, Report of Dr. William Jarvis at 16 ("It has been estimated that rather than large numbers of micro-organisms required to cause many infections, that as few as 1-10 CFUs [colony forming units] are required to cause a [periprosthetic joint infection].").
[88] *See, e.g.*, Exhibit 5, Deposition of Corporate Representative Al Van Duren at 258:5–13; 314:21-315:3.

in the operating room?[89] The authors of the study not only discovered that the internal surfaces of Bair Hugger blowers were contaminated with pathogens,[90] but the findings revealed that Bair Hugger blowers emit a multitude of particles into the surgical field.[91] An article published one year later in the AMERICAN JOURNAL OF INFECTION CONTROL, entitled *Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room*, corroborated those findings.[92] Although internal contamination of the Bair Hugger may increase the dose of bacteria exiting the device,[93] [redacted] [94] *See In re Mirapex*, 2007 WL 9636345, at *1.

Along with research showing internal contamination of the device, Defendants were aware of scientific evidence documenting another mechanism by which the Bair Hugger delivered bacteria to the surgical site—disruption of operating room airflow. In 2011, McGovern et al. published an article entitled *Forced-air warming and ultra clean*

[89] Exhibit 29, M. Albrecht, et al. *Forced air warming: a source of airborne contamination in the operating room?* ORTHOPEDIC REVIEWS (October 2009).
[90] *Id*.
[91] *Id*.
[92] Exhibit 30, M. Albrecht, et al. *Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room*. AMERICAN JOURNAL OF INFECTION CONTROL (November 2010).
[93] Exhibit E, Report of Dr. Jonathan Samet at 16.
[94] *See* Exhibit 31, Response Communication Plan – 3MBH00031537–56; *see also* Exhibit 32, Deposition of Troy Bergstrom at 93:20-94:1.

ventilation do not mix in the renowned JOURNAL OF BONE AND JOINT SURGERY.[95] The authors tested neutrally buoyant bubbles in a simulated orthopedic operation and found that heated exhaust from the Bair Hugger mobilizes unsterile air from the floor of the operating room to the surgical site.[96] The authors also compared infection rates during two periods: one with the Bair Hugger in use and one with air-free warming in use.[97] The authors identified a statistically significant risk ratio of 3.8 when the Bair Hugger was in use versus the air-free warming period. The Bair Hugger thereby increased the infection risk by 3.8.[98]

According to Plaintiffs' expert Dr. Jonathan Samet, an epidemiologist specializing in airborne particulate exposure, the McGovern study "documents a statistically significant association unlikely to be explained by confounding or other bias."[99] In other words, **based on the elevated 3.8 risk ratio reported in the study, "the Bair Hugger device would constitute a substantial contributing cause" to infections in orthopedic patients**.[100] [redacted] *See In re Levaquin*, 2010 WL 7852346, at *10 (disregarding peer-reviewed research on safety issue constitutes *prima facie* proof that defendant deliberately disregarded patient safety).

As more and more research revealed the patient safety risks of using the Bair Hugger in orthopedic surgeries, Defendants continued to deliberately disregard the truth. Based on

[95] Exhibit 32, P.D. McGovern, et al. *Forced-air warming and ultra clean ventilation do not mix*. THE JOURNAL OF BONE AND JOINT SURGERY (November 2011).
[96] *Id*.
[97] *Id*.
[98] *Id*.
[99] Exhibit E, Report of Dr. Jonathan Samet at 16.
[100] *Id*. at 17 (emphasis added).

increased temperatures and particle counts over the surgical site, two peer-reviewed studies published in 2011 found that the Bair Hugger disrupts operating room airflow and thereby causes nonsterile air to enter the sterile surgical field.[101] The same held true in 2012, as Defendants reviewed a scientific study published in the JOURNAL OF BONE AND JOINT SURGERY entitled *Forced-air patient warming blankets disrupt unidirectional airflow*[102] and another study published in ANESTHESIA & ANALGESIA entitled *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance*.[103] Both studies used neutrally buoyant bubbles to track whether excess heat from the Bair Hugger mobilized bubbles and thus particles to the surgical site. In both studies, the authors found that the Bair Hugger significantly disrupted operating room airflow near the surgical site.[104]

If those studies were not enough to demonstrate the safety risks of using the Bair Hugger in orthopedic surgeries, [redacted] a 2013 study published in the AMERICAN ASSOCIATION OF NURSE ANESTHETISTS JOURNAL entitled *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne*

[101] *See* Exhibit 34, A.J. Legg, et al. *Do forced air patient warming devices disrupt unidirectional downward airflow?* THE JOURNAL OF BONE AND JOINT SURGERY (February 2012); *see also* Exhibit 35, K.B. Dasari, et al. *Effect of forced air warming on the performance of operating theatre laminar flow ventilation*. ANAESTHESIA (March 2012).
[102] Exhibit 36, A.J. Legg, et al. *Forced-air patient warming blankets disrupt unidirectional airflow*. THE JOURNAL OF BONE AND JOINT SURGERY (March 2013).
[103] Exhibit 37, K. Belani, et al. *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance*. ANESTHESIA & ANALGESIA (August 2013).
[104] *Id*.

contamination emissions.[105] The authors evaluated the intake filtration efficiency of a Bair Hugger 750 filter and found it was only 63.8% efficient.[106] The authors also performed laboratory testing which found that 100% of Bair Huggers were contaminated with pathogenic growth.[107] Particle counting further showed that 96% of Bair Huggers were emitting significant levels of internally generated airborne contaminants out of the hose.[108] Though the researchers recommended using HEPA filtration or redesigning the device to allow for internal cleaning,[109] [redacted].[110]

All these studies provide substantial evidence of the safety risk of the Bair Hugger. Plaintiffs' expert Dr. William Jarvis, who "worked in various leadership roles at the CDC in Atlanta, Georgia, focusing on the investigation and prevention of infectious diseases," has concluded that the scientific literature includes "substantial evidence of the patient safety risk posed by the Bair Hugger."[111] The computational fluid dynamics modeling conducted by Plaintiffs' expert Dr. Said Elghobashi, along with the epidemiological

[105] Exhibit 38, M. Reed, et al. *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne contamination emissions*. AANA JOURNAL (August 2013).
[106] *Id*.
[107] *Id*.
[108] *Id*.
[109] *Id*.
[110] Exhibit 39, A.M. Wood, *Infection control hazards associated with the use of forced air warming in operating theatres*. JOURNAL OF HOSPITAL INFECTION (November 2014).
[111] Exhibit B, Report of Dr. William Jarvis at 1, 12.

findings in Dr. Samet's report, prove as much.[112] From the great weight of the literature, Defendants should have understood that the Bair Hugger has "inadequate air filtration efficiency, internal bacterial contamination (including intake and exhaust hoses), exhaust[s] microbial contaminants, interfere[s] with OR airflow (directional or non-directional), and can introduce particles/microbial contaminants into the surgical 'sterile' field."[113] [redacted]

Because Defendants' inaction in the face of these scientific studies demonstrates an intentional disregard for patient safety, Plaintiffs should be allowed to allege a claim for punitive damages. *See In re Prempro*, 586 F.3d at 572 (finding sufficient evidence to award punitive damages because a "jury could find that although each study added to the evidence suggesting a risk of [injury from use of the product], [the defendant] nevertheless continued to engage in a practice of both inaction and mitigation"); *In re Mirapex*, 2007 WL 9636345, at *9 (failure to conduct research despite "numerous reports" demonstrating negative side effect of drug provided *prima facie* evidence for plaintiffs to assert punitive damages claim); *cf*. *In re Levaquin*, 2010 WL 7852346, at *11 ("Defendants further attempt to invalidate studies cited by [plaintiff] as methodologically flawed . . . should not preclude [him] from asserting a punitive damages claim.") (citing *In re Prempro*, 586 F.3d at 573).

[112] *See* Exhibit D, Report of Dr. Said Elghobashi; *see also* Exhibit E, Report of Dr. Jonathan Samet at 9–17.
[113] Exhibit B, Report of Dr. William Jarvis at 8.
[114] Exhibit E, Report of Dr. Jonathan Samet at 16.
[115] Exhibit 40, Internal Document with Al Van Duren Comments – 3MBH00001336.

5. Defendants Know the Literature They Cite Has Significant Limits.

[redacted]

[116] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 283:1.
[117] Exhibit B, Report of Dr. William Jarvis at 13.
[118] *Id*.
[119] *Id*.
[120] *Id*.
[121] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 213:8.
[122] *Id*. at 217:9–10.

[redacted]

[redacted]”[130]

[123] Exhibit 41, 2010-09-23 Internal Email – 3MBH01223897.
[124] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 217:16–21.
[125] Exhibit 42, 2009-07-31 Moretti Study – 3MBH00001377.
[126] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 213:3–12.
[127] *Id*.
[128] Exhibit B, Report of Dr. William Jarvis at 13.
[129] *See, e.g*., Exhibit 43, 2011-03 3M Article – 3MBH00044027–28.
[130] Exhibit E, Report of Dr. Jonathan Samet at 12–13.

[redacted].[135] This evidence alone, "if unrebutted, could be relied upon at trial to find that [Defendants deliberately] disregarded the high probability of injury to the rights or safety of others." *E.g.*, *In re Mirapex*, 2007 WL 9636345, at *9.

6. Defendants Manipulated Scientific Research for Commercial Gain.

[redacted]

[131] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 291:3–9.
[132] Exhibit 44, 2013-08-03 Internal Email – 3MBH00580475.
[133] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 258:5–10 (emphasis added).
[134] Exhibit 45, 2010-03-01 Internal Email – 3MBH00050770–71.
[135] *See* Exhibit 46, 2011-03 3M Article – 3MBH00044027–28.
[136] Exhibit 47, 2010-01-21 Internal Email – 3MBH00024733.

[redacted]

[137] *Id*.
[138] *Id*.
[139] *Id*.
[140] Exhibit 48, 2010-01-17 Internal Email – 3MBH00001557.
[141] Exhibit 49, 2010-01-26 Internal Email – 3MBH00050756.

[redacted]

[142] Exhibit 16, Deposition of Dr. Daniel Sessler at 53.
[143] Exhibit 79, 2010-11-16 Internal Email – 3MBH00050932–33.
[144] Exhibit 50, 2010-10-20 Internal Email – 3MBH01223923.
[145] Exhibit 16, Deposition of Dr. Daniel Sessler at 66:24–67:1.
[146] *Id*. at 68 (emphasis added).
[147] Exhibit 51, 2010-04-23 Internal Email – 3MBH00024809.

[redacted]

[148] Exhibit 52, 2011-08-31 Internal Email – 3MBH01224622.
[149] Exhibit 53, 2012-08-31 Internal Email – 3MBH00130429.
[150] *Id*.
[151] *Id*.
[152] Exhibit 54, 2007-01-24 Internal Email – 3MBH00083780.
[153] *Id*. (emphasis added).
[154] Exhibit 55, 2007-01-24 Internal Email – 3MBH01211442.

[redacted][155]

Ironically, in this MDL, Defendants engaged in wide-ranging discovery including a series of international depositions with promises of revealing bad-faith collusion between its competitor and various researchers. All these promises turned out to be baseless, potentially defamatory allegations.[156] Instead, it is Defendants who have a history of manipulating studies, colluding with researchers, and employing scare-tactics to convince scientists not to publish adverse research.[157] This approach to research reveals Defendants' commitment to commercial goals rather than public safety. Though willing to engineer what was essentially a commercial advertisement for the Bair Hugger under the guise of actual science, Defendants failed to perform any real testing on the issue of contamination. *See In re Levaquin*, 2010 WL 7852346, at *10–12 (defendants' attempt to "manipulate[] the Ingenix Study to produce a commercially favorable result" constituted *prima facie* evidence that "would provide a jury a basis for punitive damages under Minnesota law").

7. Defendants Repeatedly Refused to Conduct a Contamination Study.

[redacted]

[155] *Id*.
[156] *See, e.g.*, Exhibit 56, Deposition of Paul McGovern at 458:1–5.
[157] *See, e.g.*, Exhibit 57, 2010-12-09 Internal Email – 3MBH00051040.
[158] Exhibit 58, Deposition of John Rock at 217:17.

[redacted]

[159] Exhibit 59, 2010-12-27 Internal Email – 3MBH00051252.
[160] Exhibit 60, 2011-03-17 Internal Email – 3MBH00575107.
[161] Exhibit 61, 2011-07-15 Internal Email – 3MBH00575251.
[162] *Id*.
[163] Exhibit 62, 2011-11-28 Internal Email – 3MBH00132501.
[164] *Id*.
[165] Exhibit 63, 2012-03-13 Internal Email – 3MBH01619270.
[166] Exhibit 64, 2010-01-06 Internal Email – 3MBH00555876.
[167] Exhibit 53, 2012-08-31 Internal Email – 3MBH00130429.
[168] *Id*.

[redacted]

[169] *Id*.
[170] *Id*. (emphasis added).
[171] Exhibit 65, 2013-03-20 Internal Email – 3MBH00134035.
[172] *Id*.
[173] Exhibit 66, 2013-04-04 Internal Email – 3MBH00107719.
[174] Exhibit 67, 2015-07-15 Internal Email – 3MBH01330587.
[175] *Id*.

[redacted][177]

[176] Exhibit 68, Deposition of Michelle Hulse-Stevens at 258:20–259:12.
[177] *Id*. at 292:7-293:4 (emphasis added).

[redacted] [181] Indeed, based on strikingly similar evidence of corporate efforts to avoid unfavorable research, Judge Noel reached a similar conclusion in the Mirapex MDL. *See In re Mirapex*, 2007 WL 9636345, at *8 (allowing plaintiffs to amend complaint to assert punitive damages claim in part because "expert consultants recommended that a study should be conducted" on side effects but defendant continually "delayed conducting [the] study"); *see also In re Prempro*, 586 F.3d at 572 (declaring that continual "failure to organize one study to allow for adequate evaluation" of side effects associated with the product would constitute *prima facie* evidence of the reckless disregard for patient safety).

[178] Exhibit 69, 2011-03-17 "War Games" Notes – 3MBH00053467.
[179] *Id*. (emphasis added).
[180] *Id*.
[181] Exhibit A, Report of Dr. Yadin David at 44.

8. Defendants Willfully Suppressed Potentially Harmful Testing.

In addition to refusing to conduct necessary testing, Defendants aggressively sought to prevent and discredit unfavorable testing of the Bair Hugger. [redacted][83] Any unfavorable research was immediately rejected without consideration, attacking the authors' methods, motives, and *bona fides*. [redacted]"[186]

[182] Exhibit 32, Deposition of Troy Bergstrom at 65–71.
[183] *Id*. at 69:7.
[184] Exhibit 70, Deposition of Jana Stender at 88:5-88:13.
[185] Exhibit 71, 2009-09-02 Internal Email – 3MBH00024680.
[186] Exhibit 72, 2010-01-14 Internal Email – 3MBH00002792.

Defendants' tactics only escalated as time went on. [redacted]

[187] Exhibit 73, 2012-08-01 Internal Email – 3MBH0125823 (emphasis added).
[188] Exhibit 32, Deposition of Troy Bergstrom at 171:6.
[189] Exhibit 73, Response Communication Plan – 3MBH00005744.
[190] Exhibit 57, 2010-12-09 Internal Email – 3MBH00051040.
[191] Exhibit 75, 2010-12-08 Internal Email – 3MBH00042660.

[redacted][193]

[redacted][196]

In the *Prempo* litigation, the Eighth Circuit discussed how a pattern of undermining clinical research of a product can support a finding of deliberate disregard of public safety:

> The district court noted that the evidence showed that [defendant] attempted to convey that there was no definitive link between [Prempro] and breast cancer. But [plaintiffs'] claim also rested on the theory that [defendant] deliberately avoided studying [Prempo's] effect on breast cancer. Moreover, a jury could reasonably construe [defendant's] documents as repeated efforts over many years to undermine information and studies that attempted to show a breast cancer

[192] *Id*.
[193] Exhibit 69, 2011-03-17 Internal Memorandum – 3MBH00053467.
[194] Exhibit 76, 2008-08-22 Internal Draft – 3MBH00108244.
[195] The Emergency Care Research Institute is a private think-tank that reviews health care technology.
[196] Exhibit 77, 2011-02-07 Internal Email – 3MBH00544754 (emphasis added).

> link. A jury reasonably could find that these efforts allowed [defendant] to promote the false understanding that [Prempo] was not linked to breast cancer and then to promote reliance on this understanding.

In re Prempro, 586 F.3d at 572. [redacted]

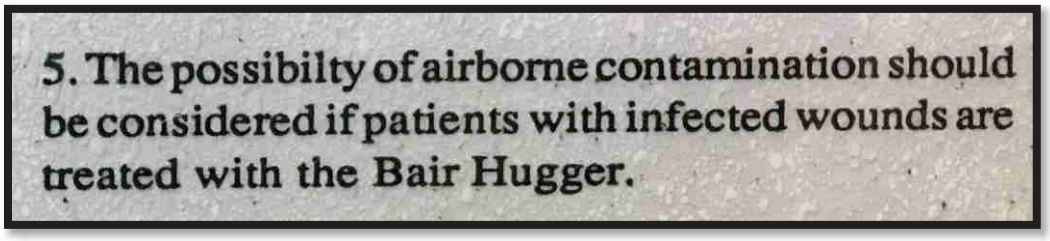
[redacted].

Plaintiffs have thus raised more than enough evidence to allege a punitive damages claim. *In re Levaquin*, 2010 WL 7852346, at *10 (allowing addition of punitive damages claim since defendants prevented action that would "negatively impact the drug's reputation").

9. Defendants Deliberately Failed to Warn of a Known Safety Risk.

Defendants also deliberately failed to warn consumers of the risks of airborne contamination. [redacted]

[redacted][98] Indeed, the Bair Hugger Model 200, which was not intended for use in operating rooms, included a warning as to the potential for airborne contamination.[199] It cautioned:



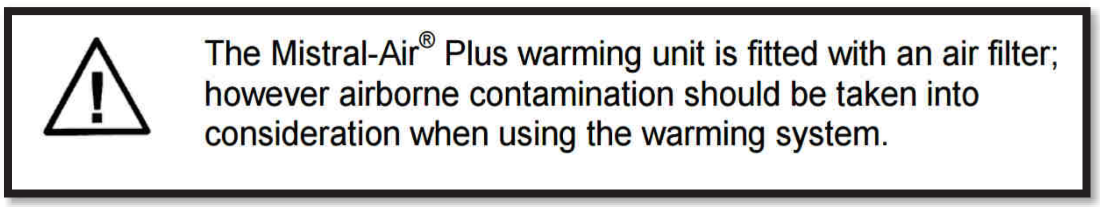
[200]

[197] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 313:21; 316:1–15.
[198] *Id*. at 316:8 (emphasis added).
[199] *Id*. at 316:14.
[200] Exhibit 9, Photograph of Bair Hugger Model 200 Warning.

[redacted]

[redacted] [201]

While Defendants removed these warnings from all later models of the device, they have not been removed from other patient-warming systems such as Stryker's Mistral-Air:



[202]

Plaintiffs' expert Dr. Yadin David discusses FDA "blue book" guidance documents which instruct device manufactures as to when a warning should be provided: "Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved."[203] Appropriate warnings would have allowed customers to "scrutinize[] the Bair Hugger's effect on operative room airflow" and to consider whether to "curtail the use of the device in high-risk orthopedic implant procedures."[204] The removal of any and all such warnings in spite of Defendants' long-standing knowledge of the attendant risks, demonstrates a

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[201] Exhibit 78, Bair Hugger Model 500 Service Manual – 3MBH02237657.
[202] Exhibit A, Report of Dr. Yadin David at 41.
[203] *Id*.
[204] *Id*.

reckless and deliberate disregard for patient safety.[205] *See In re Levaquin*, 2010 WL 7852346, at *10–12 (holding that defendants' "fail[ure] to warn [plaintiff] and his doctor of dangers, despite knowing the particular risks of tendon injury Levaquin posed to seniors using corticosteroids, and the higher risk posed by Levaquin as compared to other [drugs]," constituted *prima facie* evidence that "would provide a jury a basis for punitive damages under Minnesota law"); *In re Mirapex*, 2007 WL 9636345, at *9 (granting plaintiffs' motion to amend complaint to add punitive damages claim because they alleged that defendant had failed "to warn patients about the possible side effect" of the subject drug).

10. Defendants Cannot Challenge the Facts in this Memorandum.

Defendants may offer evidence or argument "to tell a different story, but the question before the Court is whether [Plaintiffs'] evidence, if believed in its entirety, could amount to clear and convincing proof of defendants' deliberate disregard for the right[s] and safety of others." *In re Levaquin*, 2010 WL 7852346, at *10. For example, if Defendants argue that Plaintiffs have mischaracterized or misinterpreted internal documents and employee communications, the Court must disregard such argument. *See id*. at *11 (concluding that defendants' rebuttal of plaintiff's characterizations of employee communications could not deny plaintiff "the opportunity to present his theory to a jury").

Any attempt to rebut the studies discussed in this Memorandum or to question whether Plaintiffs have proven more than an association fall fate to the same mistake. *See id*. (concluding that any "further attempt to invalidate studies cited by [plaintiff] as

[205] *Id*.

methodologically flawed and [to] defend [other studies] as more comprehensive and reliable" are nothing more than "factual disputes [that] should not preclude [plaintiff] from asserting a punitive damages claim"); *In re Mirapex*, 2007 WL 9636345, at *12 (rejecting defendants' assertion that "there has been no evidence of a cause and effect relationship" between the drug and the alleged side effect). In short, this Court should consider Plaintiffs' *prima facie* evidence without "credibility rulings," "cross-examination," or other factual challenge. *See Berczyk*, 291 F. Supp. 2d at 1008 n.3; *see also In re Mirapex*, 2007 WL 9636345, at *14 ("Whether the rebuttal evidence relied upon by Defendants is sufficient to defeat Plaintiffs' claims for punitive damages is an issue for the fact finder at trial.").

CONCLUSION

Plaintiffs have offered *prima facie* evidence of Defendants' deliberate and reckless disregard for patient safety. If fully believed, such evidence would allow a jury to find that:

- Defendants designed and marketed the Bair Hugger without performing any safety validation testing.
- Defendants cut the efficiency of the Bair Hugger filter without validating the safety of the new filters and then hid this change from the FDA and customers.
- Defendants were aware the inadequate filter of the Bair Hugger was causing internal contamination.
- Defendants could have employed design changes that would have mitigated the risk of infection but did not.
- Defendants intentionally disregarded research regarding the potential for the Bair Hugger to cause patient harm through disruption of the surgical field.

- Defendants were aware of the serious weaknesses and limits of prior research supporting the Bair Hugger.
- Defendants engineered and manipulated scientific research to produce commercially favorable results.
- Defendant sought to prevent any serious scientific inquiry into the infection risk from the Bair Hugger.
- Defendants affirmatively misrepresented Bair Hugger safety and failed to warn customers of the risk.

For these reasons, Plaintiffs respectfully move the Court for leave to amend the Master Long Form and Short Form Complaints to include a claim for punitive damages.

Respectfully Submitted,

Dated: April 21, 2017

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