IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION

Master Docket: Misc. No. 21-1230

MDL No. 3014

AFFIDAVIT OF LEE LAWLER

Before me, the undersigned authority, a Notary Public, personally appeared Lee Lawler, who first being sworn to law deposes and states:

1. My name is Lee Lawler. I am 74years old. I am currently employed by William T. Burnett ("Burnett") as the Technical and R&D Manager and I have been in that role since 2017. From 2011 until 2017, I was the Polyurethane Foam Division's Technical Director. I was hired on November 18, 2009 as a Senior Technical Analyst.

2. I graduated from Virginia Polytechnic Institute University in 1971 with a degree in Chemical Engineering. I also obtained my Masters in 1976 from West Virginia University.

3. The majority of my professional career has revolved around the technical aspects of polyurethane foam.

4. From my experience at Burnett, I have knowledge of Burnett bulk foam products, including raw materials used in the manufacturing of Burnett bulk foam. I also have knowledge of Burnett's customers. In my time with Burnett, I have been involved with virtually all inquiries from customers that were technical in nature; although the non-technical aspects of those relationships are handled separately by Burnett sales personnel. That person, as to the pertinent customers here, is Nick Vero. I understand that a separate Affidavit is being submitted by Mr. Vero contemporaneously with this Affidavit.

5. I have personal knowledge of the facts stated in this Affidavit and assert that they are true and correct based on my personal knowledge and my review of available records.[1]

6. I have also reviewed the portions of the Complaints naming Burnett as a Defendant that contain statements directed at Burnett. Many of those statements are not accurate and I am submitting this Affidavit to correct errors and misunderstandings related to: the business Burnett is in; Burnett's relationship with its customers; Burnett's position as a remote supplier of bulk foam; and Burnett's non-involvement in the development or design of (including selection of foam for) any Philips' devices at issue in this litigation.

7. I can state unequivocally that, to the extent Philips used any Burnett foam for the devices that are the subject of this litigation, Burnett was never consulted about using Burnett foam in those devices. Moreover, only in very limited instances, as discussed more fully herein, did Burnett come to learn that Philips was a customer of two Burnett customers (Polymer Technologies and SoundCoat) and that bulk commodity polyester foam manufactured by Burnett may have been used by Philips after passing through other entities. As discussed below, when Burnett received inquiries from its customer, Polymer Technologies, about the performance of foam types in certain hot and humid environments (which could have been inquiries indirectly from Philips about its devices), Burnett consistently advised against the use of less hydrolytically stable polyester foam and suggested polyether foam would perform better.

8. Burnett is a manufacturer of bulk foam. It does not supply product parts, such as the foam pieces inserted into the devices at issue in this litigation.

9. Burnett sells bulk foam to its various customers who then use the foam for their own purposes and their own customers.

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[1] Information utilized to prepare this Affidavit was assembled by counsel for Burnett and Burnett employees designated by counsel to assist in the search for information, including the undersigned. The information utilized in preparing this Affidavit was derived from an ongoing review of available Burnett business records, recognizing that some of the events which are the subject of this Affidavit occurred several years ago and, consequently, some potentially relevant documents may no longer be available due to the passage of time. I reserve the right to supplement or amend this Affidavit if new or more accurate information becomes available, or if errors or omissions are discovered.

10. Plaintiffs allege in their Complaints that Burnett foam was present in Philips' devices. Burnett has no way of knowing if any foam sold by Burnett to its customers eventually made its way into a Philips' device used by any Plaintiff. Once Burnett's foam left Burnett's control, Burnett also does not know how any Burnett foam may have been stored; how long Burnett foam may have been stored before being used; or how Burnett foam may have been altered, cut or otherwise modified.

11. Burnett does not generally deal directly with the end-users or end manufacturers of products into which Burnett foam is incorporated. Burnett generally does not interact directly with its customers' customers. To the extent any Burnett foam made its way into any Philips' devices at issue in this litigation, as explained herein, Burnett's foam necessarily passed through other entities.

12. Philips has never been a customer of Burnett. Burnett does not have any agreements or contracts with Philips and Burnett did not manufacturer or supply and/or drop ship any bulk foam to Philips or for any Philips' devices.

13. Burnett had no knowledge of, no contact with and no involvement in the development or design of any Philips' devices at issue in this litigation.

14. Burnett is not in the business of manufacturing medical devices, including any medical devices at issue in this litigation.

15. Burnett was never consulted about the selection of foam chosen by Philips or used in any Philips' devices.

16. Burnett has not had any contact with the Food and Drug Administration regarding Philips or any Philips' device at issue in this litigation.

17. Based on a review of email correspondence discussed in more detail below, two of Burnett's customers, Polymer Technologies and SoundCoat, may have taken bulk foam manufactured by Burnett and used same to supply foam to Philips or to another entity (Paramount Dye), which then may have supplied foam to Philips.

18. Burnett has no knowledge what process Polymer Technologies, SoundCoat, Paramount Dye or Philips employed to modify any bulk foam that may have been manufactured by Burnett after the foam left Burnett's control, such that the foam could be incorporated into any medical device at issue in this litigation.

19. Burnett has no way of knowing how much of Burnett's foam supplied to either Polymer Technologies or SoundCoat, if any, may have been sold to Philips or to other customers of Polymer Technologies or SoundCoat. Burnett has seen

materials from RJ Lee that suggest Philips purchased foam from another bulk foam supplier, FXI, during the periods in question. (See EX A).

20. Burnett receives orders from Polymer Technologies and SoundCoat through Purchase Orders. Burnett then acknowledges the Purchase Order. The shipment of the Order is generally accompanied by a Packing List, a label, an invoice (which contains General Terms and Conditions) and a Test report. (Exemplar documents are attached as Exhibit B).

21. Burnett's Invoice and Order Confirmation to all of its customers includes terms and conditions that explicitly state: "Due to the great number and variety of applications for which its product may be purchased, Burnett does not recommend specific applications of product designs or assume responsibility for use results obtained or suitability for specific applications." (See EX B)

22. The terms and conditions conclude with the following statement: "BULK PURCHASERS OR USERS OF POLYURETHANE FOAM SHOULD TAKE APPROPRIATE PRECAUTIONS TO ENSURE THAT IT IS PROPERLY HANDLED AND STORED AND, DEPENDING UPON THE INTENDED USE OF THE FOAM, THAT SUITABLE WARNINGS ARE PROVIDED TO THE ULTIMATE CONSUMER." (See EX B)

23. Typical foam formulations contain the following components: polyol, diisocyanate, water, catalysts, surfactants, and additives. Burnett polyurethane foam reacts a polyester or polyether polyol with toluene diisocyanate (TDI) and water in the presence of a catalyst. The end result of these formulations is a 3-D cellular structure, or foam.

24. Polyol makes up about 2/3 of foam by weight. The ingredients (major and minor) that help make foam-making possible are: polyol (50-75%), isocyanate (20-40%), water (1-4%), catalysts (0.1-1%), surfactants (0.1-3%) and additives.

25. Burnett manufactures four main types of foams: polyester; polyester with flame retardant; polyether; polyether with flame retardant.

26. Polyether foam is the most common of foams and provides excellent comfort and elasticity, better resistance to humidity and greater range of stiffness.

27. Both polyester foam and polyether foam are used for sound abatement purposes.

28. Polyester foam has increased tear, tensile and elongation, better ultraviolet stability, better solvent resistance, and better cell size control.

29. Product Specification Sheets for Burnett's 4LBFine and S82ND2 are attached as EX C.

30. The basic formulation for Burnett's 4LBFine and S82ND2 are as follows:

Formulation Basis: 100 lb.

Foam type	4LBFINE	S82ND2
Polyester polyol blend	75.24	54.95
Water	1.4	2.3
TDI	20.54	29.89
Surfactant/tertiary amine blend	2.29	1.76
Carbon black	0.53	0.11
Flame retardant	0	10.99
Net foam weight	96.6 lb.*	94.40 lb.*

* The weight difference is due to CO2 loss.

31. Recently, Philips' counsel asked a series of questions regarding two Burnett foams. These questions were different than other compositional questions posed by Philips in 2021, which I answered and which are referenced in the attached emails. The responses Burnett's counsel provided on Monday, March 28, 2022, are below. In reviewing the response to Question 1, I noticed one sentence was misplaced so in order to correct that I have prepared a supplemental answer:

1. Does the polyester fraction of DS1 foam 4LBFINE consists of diethylene glycol and adipic acid?

Answer: **Burnett purchases polyol as a raw material. The polyester polyol used to manufacture our 4LBFINE is the reaction product of diethylene glycol and adipic acid. Toluene diisocyanate is reacted with the polyester polyol and water to generate 4LBFINE. Water must be continually removed in order to drive the reaction to "completion". Completion is defined to be a specified acid number, so a small amount of adipic acid could theoretically remain in the polyol which we purchase. Water removal controls the extent of diethylene glycol conversion. During our foam making process, any residual adipic acid is likely consumed since the acid group will react with isocyanate. To our knowledge, once the foaming reaction is completed, there is no remaining diethylene glycol or adipic acid in 4LBFINE.**

Supplemental Answer: Burnett purchases polyol as a raw material. The polyester polyol used to manufacture our 4LBFINE is the reaction product of diethylene glycol and adipic acid. Water must be continually removed in order to drive the reaction to "completion". Completion is defined to be a specified acid number, so a small amount of adipic acid could theoretically remain in the polyol which we purchase. Water removal controls the extent of diethylene glycol conversion. Toluene diisocyanate is reacted with the polyester polyol and water

to generate 4LBFINE. During our foam making process, any residual adipic acid is likely consumed since the acid group will react with isocyanate. To our knowledge, once the foaming reaction is completed, there is no remaining diethylene glycol or adipic acid in 4LBFINE.

2. Is the polyester fraction of T100 S82ND2 foam low in diethylene glycol content compared to DS1 4LBFINE?

Answer: **The weight fraction of polyester polyol is lower in our S82ND2 foam than it is in our 4LBFINE foam. Therefore the portion of S82ND2 that can be attributed to the reaction of diethylene glycol and adipic acid is less in S82ND2 than it is in 4LBFINE.**

3. Are halogenated compounds used to generate the flame retardance properties in T100 S82ND2 foam?

Answer: **Yes, the flame retardant used in S82ND2 is a halogenated compound.**

4. Are chlorinated compounds used in T100 S82ND2 foam?

Answer: **Yes, the halogen in the flame retardant used to produce S82ND2 is chlorine.**

5. Are flame retardants added as additive to the formulation?

Answer: **Yes, for S82ND2. No, for 4LBFINE.**

6. Is chlorinated phthalic acid used in the formulation of S82ND2 foam?

Answer: **Not to our knowledge.**

7. Is 1,4 butanediol used in the polyester fraction of T100 S82ND2 foam?

Answer: **No. 1,4-butane diol is not used to manufacture any of the polyester polyols we use to produce S82ND2, therefore there is no 1,4-butane diol in the what you refer to as the "polyester fraction" of S82ND2.**

8. Is a propylene glycol used in the polyester fraction of T100 S82ND2 foam?

Answer: **No. To our knowledge, propylene glycol is not used to manufacture any of the polyester polyols we use to produce S82ND2, therefore there is no propylene glycol in the what you refer to as the "polyester fraction" of S82ND2.**

9. Is adipic acid used in the polyester fraction of T100 S82ND2 foam?

Answer: **Similar to what was said in answer to Question 1, Burnett purchases polyol as a raw material. The polyester polyol used to manufacture S82ND2 foam is the reaction product of diethylene glycol and adipic acid. During our foam making process, any residual adipic acid which could theoretically remain in the polyol which we purchase is likely consumed since the acid group will react with isocyanate. To our knowledge, once the foaming reaction is completed, there is no remaining diethylene glycol or adipic acid in S82ND2.**

32. Burnett foam is produced in a continuous foam machine where chemicals, per formulations, are added, mixed in an agitator at up to 6000 RPM. Foam produced is between approximately four feet to more than six feet wide and can be cured in as long as 100 feet to 200 feet lengths.

33. The Burnett bulk foam is then shipped on tractor-trailers to customers, such as Polymer Technologies and SoundCoat.

34. Plaintiffs' Complaints demonstrate a misunderstanding relating to foam degradation. Foam degradation does not mean that the foam was defective. Rather, certain environmental conditions can lead to hydrolysis and more rapid degradation of ester foams. Conditions such as high heat and humidity, for example, can cause polyester foam to degrade more rapidly than polyether foam. In contrast, polyether foam would not degrade as rapidly in a high heat and humid environment.

35. Burnett has not located any evidence that it had direct contact with representatives of Philips regarding foam Philips was using in its devices prior to late April 2021.

36. Prior to having direct contact with representatives of Philips in April 2021, based on its present investigation, Burnett believes that it first learned in April 2018 that its customer, Polymer Technologies, was supplying foam to its customer, Philips. On April 23, 2018, Bob Marsh from Polymer Technologies, emailed the undersigned regarding one of its customers finding degradation of ester foam in their device. Mr. Marsh included with his email an email from Vince Testa, Project Mechanical Engineer at Philips Home Healthcare Solutions. Mr. Marsh's email along with the forwarded Testa email are attached as EX D.

37. In his April 23, 2018 email, Mr. Marsh referenced a prior email exchange he and I had in August 2016. On August 5, 2016, Mr. Marsh and I exchanged emails regarding an unidentified customer of Polymer Technologies which had observed foam degradation in one of their medical devices after five years

of use. Mr. Marsh asked if I could give him any estimate on lifespan of the foam when exposed to 40C and high humidity. I responded "I would not be surprised if ester foam, continuously exposed to 40C (104F) at high humidity, would exhibit signs of hydrolysis in as short as a year. Intermittent exposure would extend the lifetime, but that is not a good environment for polyester foam. Polyether foam could last years in that environment." My August 5, 2016 email exchange with Mr. Marsh is attached at EX C. Mr. Marsh wrote back on August 5, 2016 stating "Thanks. I'll let them know they'd be better off with ether." See EX E.

38. Burnett has not located any information that it had any subsequent discussions or email exchanges with Polymer Technologies about its unidentified customer and polyester foam degradation due to high heat and humidity from August 5, 2016 until April 23, 2018.

39. Following up on his April 23, 2018, email, Mr. Marsh emailed me on May 2, 2018, and informed me that Philips "tested ether v. ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed." Mr. Marsh's May 2, 2018, email is attached as EX F.

40. Between May 2 and May 4, 2018, I exchanged emails with Mr. Marsh addressing questions he posed based on information he received from Philips. My May 2-4, 2018 emails with Mr. Marsh are attached as EX G. On May 3, Mr. Marsh stated that Philips was considering still using the ester foam with a scheduled replacement cycle and he asked if I could give an estimate in response to questions Mr. Testa raised in an attached email regarding foam life expectancy. Mr. Testa's email referenced foam datasheets which estimated service life at a minimum 10 years at 27C (80F) and 95% R.H. Mr. Testa stated that "[t]he environmental conditions for our device is a maximum of 40C and 95%R.H. Note the difference in temperature." See EX G.

41. I responded on May 4, 2018 and again stated that "[w]e would not recommend use of polyester foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. Polyether foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant. Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95%R.H." I also asked Mr. Marsh "Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H.? I do not think I have seen a sheet with that statement." See EX G.

42. Mr. Marsh responded on May 4, 2018 that he would pass on my comments to his customer. He also states "We have no idea where that statement came

from. It has been on our data sheets for probably 20 years. We are removing it." See EX G.

43. I believed in May 2018, and have confirmed, that Burnett Specification sheets for polyester foam never contained any statements indicating that polyester foam lifetime would be a minimum 10 years at 95% R.H.

44. On May 23, 2018, Mr. Marsh and I exchanged emails relating to flammability rating of foam. My May 23, 2018, emails with Mr. Marsh are attached as EX H.

45. On June 7, 2018, Mr. Marsh forwarded to me an email from Mr. Testa asking several questions relating to the composition of Burnett foam. Mr. Marsh's June 7, 2018, email is attached as EX I. Thereafter, given the proprietary nature of what was being sought, I questioned Mr. Marsh as to why Mr. Testa needed this information. See my email exchange with Mr. Marsh dated June 14, 2018, attached as EX I. Mr. Marsh responded that Mr. Testa told him "they are investigating alternatives to polyurethane foam (ester and ether) due to the exposure of the absorber to pure oxygen. Why they need the ingredients of what they are using is a good question. Perhaps they are trying to figure out which compound is reacting so they can avoid it in another material." See EX I. Since I did not fully understand why this information was being sought and was not comfortable disclosing any confidential compositional information I ultimately did not respond to Mr. Marsh.

46. Burnett has not located any evidence of further communications with Burnett customer, Polymer Technologies, regarding Philips or foam used in its devices between June 2018 and May 2021.

47. In May 2021, I learned from Mr. Mike Haupt at Polymer Technologies that Polymer Technologies had accidentally sent Philips ester foam instead of ether foam. See EX J. This resulted in a series of emails and at least one phone call which I participated in with representatives of Philips and Polymer Technologies. My notes summarizing that call on May 21, 2021 are attached as EX K. Emails relating to this issue, including spot testing that Burnett undertook on Polymer Technologies foam at their request, are attached collectively as EX L.

48. Between April 27, 2021, and November 23, 2021, Burnett representatives, including the undersigned, had email exchanges with representatives of Burnett's customer, SoundCoat, and, on occasion, representatives of Philips, and representatives of Paramount Dye, requesting information from Burnett regarding its foam. Those emails are attached collectively as EX M.

49. For example, on May 4, 2021, I emailed our customer, SoundCoat, and provided answers to a series of questions which came from Philips seeking information about the composition of Burnett's 4 LB Fine foam. See EX N. On

May 24, 2021, Philips posed additional questions to which I responded. These May 24, 2021 emails are attached at EX O.

50. Philips, either directly or through SoundCoat, posed additional questions in September, October and November 2021 relating to the composition of Burnett foam and I provided responses to those inquiries. See emails from 2021 dated September 13, 14, October 11, and November 23, attached as part of EX M.

51. Burnett stands behind all foam it supplied to its customers, Polymer Technologies and SoundCoat. Any foam Burnett supplied to either Polymer Technologies or SoundCoat was not defective. Burnett does not have knowledge sufficient to comment on what was done to Burnett foam after it left Burnett's control and passed through other entities to the point where it may have made its way into any Philips' device. Consistent with what I informed our customer, Polymer Technologies, in 2016 and 2018, if any Burnett polyester foam was used in an environment that subjected the foam to high heat and humidity, such foam was incorrect for that application.

Further Affiant sayeth not.

Lee Lawler

Lee Lawler

SWORN TO and subscribed

before me this 1st day

of April, 2022.

Notary Public

MISTY PUCKETT NOTARY PUBLIC FLOYD COUNTY, GA EXP. Sept. 20, 2025

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