

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

PAMELA BELL,)	
)	
Plaintiff,)	
)	
vs.)	
)	Case No. 1:11-cv-01454-TWP-MJD
PAR PHARMACEUTICAL COMPANIES,)	
INC.,)	
PAR PHARMACEUTICAL, INC.,)	
)	
Defendants.)	

ENTRY ON MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.’s (collectively, “Par”) Motion for Summary Judgment (Dkt. 52) and Motion to Strike Photographs and Related Testimony (Dkt. 61), and Plaintiff Pamela Bell’s (“Ms. Bell”) Motion to Strike the Declaration of Barbara H. Ost and Portions of the Declaration of T. Duane Gosser (Dkt. 59). Par seeks summary judgment on Ms. Bell’s claims that medication sold by Par contained foreign objects, specifically pieces of latex gloves and blood. For the reasons set forth below, Ms. Bell’s motion to strike (Dkt. 59) is **DENIED**, Par’s motion to strike (Dkt. 61) is **GRANTED**, and Par’s motion for summary judgment (Dkt. 52) is **GRANTED**.

I. FACTUAL BACKGROUND

The following material facts are not in dispute.¹ Par Pharmaceuticals, Inc. is a pharmaceutical company that sells cholestyramine powder, a prescription drug designed to lower

¹ As discussed in further detail below, Ms. Bell failed to provide a Statement of Material Facts in Dispute section in her brief in opposition to Par’s motion, as required by Local Rule 56-1(b). Accordingly, the Court will accept the facts as set forth by Par consistent with Local Rule 56-1(f).

high levels of cholesterol in the blood and as a digestive aid to treat blockages in the bile ducts of the gallbladder. Par Pharmaceutical Companies, Inc. is the holding company for Par Pharmaceuticals, Inc. and does not itself manufacture or sell cholestyramine powder.² The cholestyramine powder sold by Par is manufactured in bulk by Calatent Parma Solutions, Inc. (“Calatent”), and then shipped to Sharp Corporation (“Sharp”) which packages bulk cholestyramine into individual cans. The manufacturing and packaging of bulk cholestyramine is governed by applicable regulations known as the current Good Manufacturing Practices approved by the United States Food and Drug Administration (“FDA”), set forth in 21 C.F.R. Parts 210 and 211 (“cGMPs”). Both Calatent and Sharp maintain batch records and process logs, which document the events that occur during the manufacturing and processing of each lot of cholestyramine powder. At the time the cholestyramine at issue was manufactured and packaged in March 2009, there were no reported injuries or accident reports noted in the batch records at Calatent or Sharp, and the manufacturing and packaging of the medication was done in accordance with the cGMPs.

Ms. Bell was prescribed cholestyramine mixture for treatment of her high cholesterol after having her gallbladder removed in 2007. In June 2009, she purchased five cans of cholestyramine powder sold by Par from lot number 21946901. On the morning of July 24, 2009, Ms. Bell took one scoop of the cholestyramine powder from a can she had previously opened and used, put the powder in a cup, added some bottled water, mixed it, let it sit to dissolve, and then proceeded to drink the mixture. Ms. Bell said she consumed some of the cholestyramine mixture, and in doing so, she felt something in her mouth. She immediately spat

² Defendants assert that Par Pharmaceutical Companies, Inc. is merely a holding company that has not manufactured or sold cholestyramine powder, and thus is entitled to dismissal for that reason. Dkt. 53 at 1 n.1. Par provides no additional argument or authority to support this assertion; however, the Court has determined that it need not expressly make this determination for the reasons set forth in this Entry.

the contents of her mouth back into the same cup and noticed, for the first time, that the mixture was a “blood red” color,³ when typically the mixture from the same container was a light orange color. Ms. Bell also claims she noticed two objects in her cup, one of which was the object she had spat back into the cup. Upon scooping one of the two pieces out of the cup, she observed an off-white colored latex glove fingertip. She testified in her deposition that it was about an inch long with a jagged cut at one end. The second piece was another latex glove fingertip of the same size, color and jagged cut. Ms. Bell was home alone on the morning of July 24, 2009, but her roommate, Carolyn Moorehead (“Ms. Moorehead”), came home later that evening and Ms. Moorehead also observed the latex pieces in the cup.

As a result of her alleged contact with the latex glove fingertip and the mixture that she believed contained blood, Ms. Bell claims she suffered from nausea for half a day, however, she did not seek any medical treatment. Ms. Bell underwent three tests for blood-borne diseases, but she never tested positive for any condition resulting from exposure to foreign blood. She claims that she continues to have anxiety and worry, but has never been diagnosed by any healthcare provider with any physical or mental condition as a result of the incident, and has never sought or received any counseling or therapy.

Ms. Bell has been unable to produce the latex pieces that were allegedly in her cholestyramine mixture. Ms. Bell testified that she left the cup and its contents on a nightstand in her bedroom from the morning of the incident until October 14, 2009. Following the incident, Ms. Bell contacted her attorney and on July 30, 2009 her counsel notified Par by letter of Ms. Bell’s claims. At the direction of her attorney, Ms. Bell put the cup in a plastic bag and stored it in her refrigerator until she brought it to her deposition on April 11, 2012. However, the cup

³ Ms. Bell has testified in her deposition both that the mixture was a dark reddish-brown color and that it was a bright blood red color. Dkt. 53-2 at 7:19-9:2.

brought to the deposition contained only evaporated cholestyramine mixture, but no pieces of latex. Although the cup was in the sole custody of Ms. Bell from July 24, 2009 until the date of her deposition, she has provided no explanation as to where the latex pieces went, aside from her deposition testimony that she believed that the latex pieces had degraded in the cup. However, an expert retained by Par states that latex would not have degraded during the three years from the date of the incident under the conditions in which the cup was stored.

Ms. Bell repeatedly asserted throughout discovery and testified at her April 11, 2012 deposition, that she never took any photographs of the latex glove fingertips in the cup, despite owning a camera at the time. However, five months after Ms. Bell's deposition, and three years after the alleged incident, Ms. Bell's roommate, Carolyn Moorehead, testified at her deposition that Ms. Bell suddenly recalled during the week of September 17, 2012 that she and Ms. Bell did take photographs of the cup on the evening of July 24, 2009. Ms. Moorehead brought copies of these photographs to her deposition on September 28, 2012. Despite both women allegedly participating in the photographing of the cup and latex pieces, Ms. Bell offers no explanation as to why she did not recall that they had taken the photographs until September 2012. Additional facts will be provided below as necessary.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 56 provides that summary judgment is appropriate if “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” *Hemsworth v. Quotesmith.Com, Inc.*, 476 F.3d 487, 489–90 (7th Cir. 2007). In ruling on a motion for summary judgment, the court reviews “the record in the light most favorable to the nonmoving party and draw[s] all reasonable

inferences in that party's favor." *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009) (citation omitted). However, "[a] party who bears the burden of proof on a particular issue may not rest on its pleadings, but must affirmatively demonstrate, by specific factual allegations, that there is a genuine issue of material fact that requires trial." *Hemsworth*, 476 F.3d at 490 (citation omitted). "In much the same way that a court is not required to scour the record in search of evidence to defeat the motion for summary judgment, nor is it permitted to conduct a paper trial on the merits of a claim." *Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001) (citation and internal quotations omitted). "[N]either the mere existence of some alleged factual dispute between the parties . . . nor the existence of some metaphysical doubt as to the material facts . . . is sufficient to defeat a motion for summary judgment." *Chiaromonte v. Fashion Bed Grp., Inc.*, 129 F.3d 391, 395 (7th Cir. 1997) (citations and internal quotations omitted).

III. DISCUSSION

A. Motions to Strike

As a preliminary matter, the Court must address the challenges that each party make as to evidence offered by the opposing party in support of their briefs. Ms. Bell has moved for the Court to strike the declaration of Barbara H. Ost of Sharp Corporation, and to strike portions of the declaration of T. Duane Gosser of Catalent Pharma Solutions, Inc. presented by Par in support of their motion for summary judgment (Dkt. 59). Par has moved the Court to strike photographs of the cup of cholestyramine mixture and related testimony from Ms. Moorehead presented by Ms. Bell in her opposition to Par's motion for summary judgment (Dkt. 61).

1. Declarations of Barbara H. Ost and T. Duane Gosser

Ms. Ost, the Vice President Quality Assurance Manager at Sharp and Mr. Gosser, the Quality Assurance Manager for Catalent, have each submitted a declaration regarding their company's

investigation of Ms. Bell's allegations. Ms. Bell argues that the declaration of Barbara Ost (Dkt. 53-5) and portions of the declaration of T. Duane Gosser (Dkt. 53-4) should be stricken because they contain inadmissible evidence. Specifically, Ms. Bell argues that Ms. Ost's declaration is not based upon any personal knowledge, and portions of Mr. Gosser's declaration contain statements which are inadmissible hearsay, are not based on personal knowledge, or are legal conclusions. Ms. Bell asserts that because Ms. Ost and Ms. Gosser did not personally observe the manufacturing and packaging of the cholestyramine powder, they lack the requisite personal knowledge to make their declarations admissible.

Federal Rule of Civil Procedure 56(c)(4) provides that affidavits or declarations used to support or oppose a motion for summary judgment must be made on personal knowledge and set forth facts that would be admissible under the Federal Rules of Evidence. In addition, Federal Rule of Evidence 602 provides that declarants who are not expert witnesses are permitted to testify only from their personal knowledge. However, "there is a general presumption that an employee or corporate representative has personal knowledge, sufficient to attest to matters relating to the business entity." *St. Paul Fire & Marine Ins. Co. v. Schilli Transp. Svcs., Inc.*, No. 2:08-cv-176, 2011 WL 1743480, *4 (N.D. Ind. May 5, 2011), *rev'd on other grounds*, 672 F.3d 451 (7th Cir. 2012). It is irrelevant as to whether this knowledge was gained from reviewing documents that the company had a business duty to record, or from the officer's or employee's personal observation. *Id.* at *5. In addition, "Federal Rule of Evidence 803(6) exempts from the definition of hearsay statements contained in business documents made at or near the time of an event, recorded by someone with personal knowledge, kept in the regular course of business, and made by someone under a business duty to record." *Id.*

Mr. Gosser was the Quality Assurance Manager for Calatent from February 2009 until July 2012, during the time period that the cholestyramine powder purchased by Ms. Bell was manufactured. Ms. Ost has been the Vice President Quality Assurance Manager for Sharp Corporation from August 2010 to present. Although Ms. Ost was not the Quality Assurance Manager at the time the cholestyramine powder at issue was packaged, she reviewed the batch records from the relevant time period and conducted the investigation related to this litigation. Both individuals are entitled to the presumption that they have personal knowledge sufficient to attest to matters relating to Calatent and Sharp, respectively. Each of their declarations are based upon investigations into the records kept during the time the cholestyramine powder at issue was manufactured and packaged, providing sufficient personal knowledge to make the facts contained therein admissible. Additionally, Mr. Gosser's statements regarding Calatent's manufacturing practices being in accordance with the cGMPs is not a legal conclusion; rather, it is the type of lay opinion that would be admissible at trial under Federal Rule of Evidence 701. *See Medline Indus., Inc. v. Cymbion, LLC*, No. 09 C 581, 2010 WL 4736315, *11 n.11 (N.D. Ill. Nov. 16, 2010)(witness's opinion regarding compliance with certain FDA regulations is the type of lay opinion which would be admissible at trial). Therefore, Ms. Bell's motion to strike these declarations, in whole or in part, is **DENIED**.

2. Photographs and related testimony

Par has filed a motion to strike photographs and related testimony provided by Ms. Bell in support of her opposition to Par's motion for summary judgment (Dkt. 61). During her deposition on September 28, 2012, Ms. Moorehead brought photographs which purported to show two latex pieces in the cup of cholestyramine mixture consumed by Ms. Bell on July 24, 2009. Par objects to this evidence due to the fact that September 2012 is the first time that the

photographs were produced, and the first time their existence was even revealed. Par states that throughout discovery, Ms. Bell was repeatedly asked and required to disclose the existence of any photographs, including in her response to an October 11, 2011 request for production, her March 29, 2012 preliminary witness and exhibit list, and at Ms. Bell's April 11, 2012 deposition. On all these occasions, Ms. Bell testified under oath that the cup and the remaining cholestyramine mixture were never photographed, even after being questioned at length at her deposition about whether the cup was photographed or videotaped, and what type of camera she owned and how often she used it. Dkt. 52-3 at 36-37, 78:13-79:13. Ms. Bell also did not disclose the existence of the photographs in her final witness and exhibit lists in September 2012, and in her summary of Ms. Moorehead's testimony, Ms. Bell stated only that Ms. Moorehead would be testifying as to Ms. Bell's demeanor following the incident and her observation of the liquid and the objects in the liquid on the day of the incident. The summary did not mention the photographs or that Ms. Moorehead would be providing any testimony about the photographs.

Rule 37(c)(1) of the Federal Rules of Civil Procedure provides that

[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.

Fed. R. Civ. P. 37(c)(1). Rule 26(e) imposes upon a party a duty to supplement or correct its disclosures and discovery responses in a timely manner if the party learns that the disclosure or response is incomplete or incorrect in some material respect. Fed. R. Civ. P. 26(e). "The exclusion of non-disclosed evidence is automatic and mandatory under Rule 37(c)(1) unless non-disclosure was justified or harmless." *Musser v. Gentiva Health Svcs.*, 356 F.3d 751, 758 (7th Cir. 2004).

Ms. Bell has not provided any explanation that would lead the Court to conclude that the failure to disclose the photographs prior to September 28, 2012 is substantially justified or harmless; in fact, Ms. Bell did not even respond to Par's motion to strike. There is no justification, whatsoever, in the record as to why Ms. Bell repeatedly asserted that there were no photographs taken of the cup but later produced them at Ms. Moorehead's deposition. In her deposition, Ms. Moorehead testified that both she and Ms. Bell, who Ms. Moorehead claims were both present when the alleged photographs were taken, simply forgot about them until three years later. Dkt. 57-1 at 2, 25:1-21. However, Ms. Moorehead's testimony still does not speak to Ms. Bell's justification for failing to disclose the existence of the photographs, and Ms. Bell has provided none.

In addition, the Court cannot say that Ms. Bell's failure to disclose the photographs and related testimony is harmless. "[T]he following factors should guide the district court's discretion: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date." *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003). The photographs depict the evidence that is central to this case—the latex glove pieces that were allegedly in Ms. Bell's cholestyramine powder. This photographic evidence is particularly important to Par considering the inexplicable disappearance of the actual latex pieces themselves. The fact that they were not disclosed until a little over two weeks before the dispositive motions deadline, after repeated inquiries about and requests for their disclosure, has placed Par at a disadvantage in the preparation of their case. Because Ms. Bell has offered no substantial justification for her failure to disclose the

photographs prior to September 2012 and because this failure to disclose is prejudicial to Par, the Court finds that the sanction of exclusion under Rule 37(c)(1) is appropriate in this case.

Par's motion to strike the photographs and related testimony is **GRANTED**. The Court will not consider the photographs or the portions of Ms. Moorehead's testimony regarding those photographs in its consideration of Par's motion for summary judgment.⁴

B. Summary Judgment

1. Failure to comply with Local Rule 56-1(b)

Local Rule 56-1(b) states that the non-movant's response "*must* include a section labeled 'Statement of Material Facts in Dispute' that identifies the potentially determinative facts and factual disputes that the party contends demonstrate a dispute of fact precluding summary judgment." S.D. Ind. Local R. 56-1(b) (emphasis added). Local Rule 56-1(f) states that the court will assume that the facts as claimed and supported by the movant are admitted without controversy except to the extent that the non-movant specifically controverts the facts in its "Statement of Material Facts in Dispute." S.D. Ind. Local R. 56-1(f). The consequence of the non-movant's failure to include a statement of material facts in dispute as mandated by the local rules results in an admission of the facts as set forth by the moving party. *Smith v. Lamz*, 321 F.3d 680, 683 (7th Cir. 2003). "[A] mere disagreement with the movant's asserted facts is inadequate if made without reference to specific supporting material." *Id.* Strict compliance with Local Rule 56-1 is expected and required. *Cichon v. Exelon Generation Co., L.L.C.*, 401

⁴ Even if the Court were to permit Ms. Bell to use the photographs in support of her opposition, the photographs would only hurt, not help, her case. The objects in the photograph contradict Ms. Bell's deposition testimony that the pieces were both one inch, off white, and jagged cut, as the photographs show two uneven pieces of different color and length with straight cuts on the ends. While the Court may not weigh evidence at summary judgment, where a witness's story is so internally inconsistent or implausible on its face that a reasonable fact finder would not credit it, the Court may reject the testimony without trial. *Seshadri v. Kasraian*, 130 F.3d 798, 802 (7th Cir. 1997) (citing *Anderson v. City of Bessemer City*, 470 U.S. 564, 575 (1985)). However, because this evidence has been excluded under Rule 37(c)(1), the Court need not explicitly make this determination.

F.3d 803, 809 (7th Cir. 2005). “[I]n imposing a penalty for a litigant’s non-compliance with Local Rule [56-1], the court [may choose] to ignore and not consider the additional facts that a litigant has proposed.” *Id.* at 810.

Ms. Bell’s brief does not include a “Statement of Material Facts in Dispute” section as required by Local Rule 56-1(b). In addition, Ms. Bell specifically states that she does not dispute any of the material facts set forth by Par in its motion for summary judgment, and only asserts additional facts from the deposition of Ms. Moorehead regarding the photographs of the cholestyramine mixture, and Ms. Bell’s deposition testimony regarding her doctor’s recommendation that she undergo blood tests. Dkt. 58 at 4-5. As stated above, the Court has stricken the portion of Ms. Moorehead’s testimony regarding the photographs, and it will not be considered in determining whether there is a disputed material fact. The Court will consider the fact that Ms. Bell underwent medical testing at her doctor’s recommendation; however this evidence presents no disputed material facts.

Because Ms. Bell has failed to comply with Local Rule 56-1(b), the Court will accept Par’s statement of facts as true for purposes of this motion. Thus the only thing the Court must determine is, under the facts as presented by Par, whether Par is entitled to judgment as a matter of law. “Where there is no genuine issue of material fact, the sole question is whether the moving party is entitled to judgment as a matter of law.” *Ortiz v. John O. Butler Co.*, 94 F.3d 1121, 1124 (7th Cir. 1996). Under the set of facts as presented by Par, if Ms. Bell fails to establish the existence of an element essential to her case, one on which she would bear the burden of proof at trial, summary judgment must be granted to Par. *Id.*

2. Indiana Products Liability Act

Although Ms. Bell does not specifically reference the Indiana Products Liability Act in

her Complaint, her claims are governed by it. “[T]he Indiana Products Liability Act (“IPLA”), Indiana Code sections 34-20-1-1 through 34-20-9-1, governs all actions brought by a user or consumer against a manufacturer or seller for physical harm caused by a product, regardless of the legal theory upon which the action is brought.” *Hathaway v. Cintas Corporate Servs., Inc.*, No. 1:10 CV 195, 2012 WL 4857828, *3 (N.D. Ind. Oct. 11, 2012) (citing I.C. § 34- 20-1-1). The IPLA imposes liability for physical harm caused by a product in an unreasonably dangerous and defective condition. *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010). “A product may be defective within the meaning of the Act because of a manufacturing flaw, a defective design, or a failure to warn of dangers in the product’s use.” *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997) (citing *Hoffman v. E.W. Bliss Co.*, 448 N.E.2d 277, 281 (Ind. 1983)).

Ms. Bell essentially argues that the can of cholestyramine powder contained a manufacturing defect; specifically, that something went wrong in the manufacturing process to cause two latex glove fingertips, and what appeared to her to be blood, to end up in her medication. “A product contains a manufacturing defect when it deviates from its intended design.” *Westchester Fire Ins. Co. v. Am. Wood Fibers, Inc.*, No. 2:03-CV-178-TS, 2006 WL 3147710, at *5 (N.D. Ind. Oct. 31, 2006). Ms. Bell certainly does not argue that Par intended for latex glove pieces to be included in the design of the cholestyramine powder, nor does she argue that Par failed to warn her about the foreign objects in her medication. Therefore, the Court will address Ms. Bell’s claim as a manufacturing defect claim under the IPLA.

a. Presumption of non-defectiveness

Section 34-20-5-1 of the IPLA contains a rebuttable presumption that a product is not defective and the manufacturer or seller is not negligent if, before the sale by the manufacturer,

the product complied with applicable codes, standards, regulations, or specifications established by the United States or Indiana, or by an agency of the federal government or state of Indiana. I.C. § 34-20-5-1. Once the presumption is established, the opposing party has a burden of producing evidence to overcome the presumption and avoid dismissal. *See Cansler v. Mills*, 765 N.E.2d 698, 705 (Ind. Ct. App. 2002), *overruled on other grounds by Schultz v. Ford Motor Co.*, 857 N.E.2d 977 (Ind.2006); *see also McClain v. Chem-Lube Corp.*, 759 N.E.2d 1096, 1101 (Ind. Ct. App. 2001) (“[A] rebuttable presumption does not shift the burden of proof but it does impose upon the opposing party a burden of producing evidence.”).

Par has demonstrated that the rebuttable presumption under the IPLA applies to the cholestyramine consumed by Ms. Bell. Par has provided the declarations of quality assurance personnel from both Sharp and Calatent as evidence that the cholestyramine powder at issue was manufactured and packaged in accordance with the cGMPs approved by the FDA. There are no indications in the batch records from either company that Sharp and Calatent deviated from these practices at the time lot number 21946901 was manufactured and packaged, and Ms. Bell does not present evidence of any disputed facts on this issue. Dkts. 53-4 at 2-3; 53-5 at 2-3. Therefore, there is a presumption under the IPLA that the cholestyramine powder was not defective.

b. Ms. Bell fails to rebut the presumption of non-defectiveness

To overcome the presumption that the cholestyramine powder was not defective, Ms. Bell must present sufficient evidence to prove the following elements: (1) she was harmed by a product; (2) the product was sold “in a defective condition unreasonably dangerous to any user or consumer”; (3) she was a foreseeable user or consumer; (4) Par was in the business of selling the product; and (5) the product reached Ms. Bell in the condition it was sold. *Bourne v. Marty*

Gilman, Inc., 452 F.3d 632, 635 (7th Cir. 2006) (quoting I.C. § 34–20–2–1). Indiana law requires the plaintiff to show that a product is both “in a defective condition” and that it is “unreasonably dangerous.” *Id.*

Ms. Bell cannot show that the product was in a defective condition when it left Par’s control. She has no evidence of the latex pieces in question, the very things she alleges made the cholestyramine powder defective. Ms. Bell has not provided any explanation as to where the latex pieces went, aside from her assumption that they must have disintegrated over time. Dkt. 53-2 at 41:5-16. However, Par has presented expert testimony showing that it would have been impossible for the latex pieces to disintegrate or degrade under the conditions which the cholestyramine mixture was stored since the date of the incident, a fact which Ms. Bell does not dispute. Ms. Bell also has not presented any expert testimony or other evidence that would provide a contradictory explanation as to what happened to the missing latex pieces, nor has she presented any expert testimony as to whether there was blood in the cholestyramine mixture. Thus, Ms. Bell has not presented evidence that the cholestyramine powder contained a defect. Ms. Bell’s failure to produce evidence of the latex pieces, along with Par’s other undisputed evidence, is simply a lack of proof of an essential element of her claim. Consequently, the Court need not determine whether the disappearance of the latex pieces warrants the sanction of dismissal.

But, even if the Court were to accept Ms. Bell’s otherwise unsupported assertion that there were pieces of latex in her cup of cholestyramine mixture on the day of the incident, she has not presented any evidence that would show that the latex pieces came from Par, which is a necessary element of causation in a products liability action. Ms. Bell argues that she may use one of the four methods of proof articulated by the Seventh Circuit in *Whitted v. Gen. Motors*

Corp., 58 F.3d 1200 (7th Cir. 1995), to prove that the defect existed when the can of cholestyramine powder left Par's control, including "introduc[ing] inferential evidence by negating other possible causes." *Id.* at 1207. Ms. Bell claims that she has done this by introducing the photographs of the cup and related testimony, creating a fact for the jury to decide. Aside from the fact that this purported evidence has already been stricken by the Court, Ms. Bell misapplies this test, as the court in *Whitted* was applying the theory of *res ipsa loquitur* to prove that a manufacturing defect existed, which necessarily requires that "the injuring instrumentality be in the exclusive control of the defendant at the time of injury." *Id.* The can of cholestyramine powder was in Ms. Bell's control at the time of the alleged injury, and she had previously opened and consumed medication from the same can. Ms. Bell does not present any other admissible evidence that would create a question of fact as to whether the latex pieces were in the cholestyramine powder at the time it was sold.

However, Par has presented undisputed evidence that there were no reported accidents or work stoppages at either Calatent or Sharp during the manufacturing and packaging of lot number 21946901, which would have been documented in Sharp's and Calatent's batch records at the time they occurred. Dkts. 53-4, 53-5. Par has also presented undisputed evidence that the latex pieces could not have entered the can of cholestyramine powder at the manufacturing facility, because the gloves used by employees at Calatent at the time were blue nitrile gloves, not off-white latex gloves. Dkt. 53-4 at 3 ¶ 6. In addition, Par has presented undisputed evidence that the packaging process at Sharp would have detected the presence of foreign objects in the can in question based upon weight measurements, and there were no reports of any cans being overweight in that particular lot. Dkt. 53-5 at 3 ¶ 9. Because Ms. Bell does not dispute any of these facts and has not presented any evidence contrary to the presumption that the can of

cholestyramine powder was not defective under the IPLA, summary judgment should be entered in favor of Par.

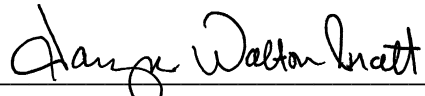
Finally, Ms. Bell’s claims fail for the additional reason that she cannot show she was harmed by the product. A manufacturer is only liable if the consumer suffers “physical harm caused by [the] product” to herself or her property. I.C. § 34-20-2-1. “‘Physical harm’, for purposes of IC 34-20, means bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property.” I.C. § 34-6-2-105. Ms. Bell has not presented any medical records or other evidence showing that she suffered any bodily injury from her consumption of the cholestyramine mixture. She testified only that she experienced nausea for half a day immediately following the incident, and the results of blood tests that she underwent all came back normal. Aside from the negative blood tests, she has not sought medical treatment for any condition that she alleges arose from the incident. Because Ms. Bell cannot prove an essential element of her claim—that she was injured by the cholestyramine product—Par is entitled to summary judgment. *See Progressive Ins. Co. v. Gen. Motors Corp.*, 749 N.E.2d 484, 488 (Ind. 2001) (“[The Supreme Court of Indiana] has consistently interpreted the Products Liability Act to bar a tort action where no damage to person or other property is present”).

IV. CONCLUSION

For the reasons set forth above, Pamela Bell’s motion to strike (Dkt. 59) is **DENIED**. Par Pharmaceutical Companies, Inc.’s and Par Pharmaceutical, Inc.’s motion to strike (Dkt. 61) and motion for summary judgment (Dkt. 52) are **GRANTED**.

SO ORDERED.

Date: 05/21/2013



Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

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