UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

NATARSHA HARRIS, *individually and as parent and guardian of X.X.*, JESSICA DIONISE, individually and as parent and guardian of R.D., *on behalf of themselves and all others similarly situated*,	:	**Case No.**
Plaintiffs,	:	
- against -	:	
KIMBERLY-CLARK CORPORATION,	:	
Defendant.	:	

DECLARATION OF FRANK FRITZ KROMENAKER

I, Frank Fritz Kromenaker, declare as follows:

1. I make this declaration pursuant to 28 U.S.C. § 1746. Unless otherwise noted, the statements made herein represent my own first-hand knowledge. If called upon to testify as to them, I could and would do so competently.

2. I have been retained by Plaintiffs' counsel as a hybrid fact witness/consultant owing to both my first-hand knowledge of Kimberly-Clark operations and my technical expertise in Kimberly-Clark manufacturing process. Though I am being compensated, this has not compromised my objectivity. As explained below, I arrived at my views regarding Kimberly-Clark's reckless indifference to consumer safety long before the filing of this action.[1]

[1] *See Prasad v. MML Inv'rs Servs.*, 2004 U.S. Dist. LEXIS 9289, at *19 (S.D.N.Y. May 24, 2004) ("That a fact witness has been retained to act as a litigation consultant does not, in and of itself, appear to be improper, absent some indication that the retention was designed as a financial

BIOGRAPHY AND EXPERIENCE

3. I worked for Kimberly-Clark from January 30, 1989, to November 2, 2011, at various Kimberly-Clark facilities in Neenah, Wisconsin.

4. Kimberly-Clark is a multinational corporation headquartered in Irving, Texas that manufactures a range of products, including drugs, medical clothing such as masks, gloves, surgical gowns, sterile wraps, medical supplies, medical devices such as endotracheal tubes, feeding tubes, and pain management systems. Kimberly-Clark also manufactures Kleenex, infant care products such as Huggies and Little Swimmers, adult care products such as Poise, and feminine hygiene products such as Kotex.

5. Most of my tenure was at Kimberly-Clark's Research and Engineering facility. This was followed by two years at Kimberly-Clark's Feminine and Adult Care facility and then two years at Kimberly-Clark's FDA Compliance Testing Facility. The work done at these facilities plays in important role in the design of new products and the improving of existing ones because it is at these facilities that product specifications are developed. So, too, are specifications for the machines that manufacture Kimberly-Clark products. These facilities develop and test the custom instruments that ensure the machines are functioning as intended when used to manufacture

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inducement or as a method to secure the cooperation of a hostile witness, or was otherwise improper."); *Klorczyk v. Sears*, No. 3:13-cv-00257 (JAM), 2017 U.S. Dist. LEXIS 120234, at *6-7 (D. Conn. Aug. 1, 2017) ("Although the rule at common law prohibited compensating fact witnesses in any manner, the common law rule has been relaxed over time. The ABA's Formal Ethics Opinion interpreting ABA Model Rule 3.4 (which in relevant respects is identical to Connecticut's Rule 3.4) advises that non-expert witnesses may be compensated not only for time spent testifying but also for time spent preparing to testify, as long as payment is not conditioned on the content of the witness's testimony and does not violate the law of the jurisdiction… Other courts within the Second Circuit have echoed this position…"); *New York v. Solvent Chem. Co.*, 166 F.R.D. 284, 290 (W.D.N.Y. 1996) ("Of course, the court finds nothing improper in the reimbursement of expenses incurred by Mr. Beu in travelling to New York to provide ICC with factual information, or in the payment of a reasonable hourly fee for Mr. Beu's time.")

Kimberly-Clark products, including Huggies diapers. Once these testing instruments are designed, they are mass-produced and distributed globally to Kimberly-Clark's manufacturing facilities, contract manufacturing facilities, and contract testing companies.

6. I began my twenty-two-year career at Kimberly-Clark in a facilities management role where I calibrated and repaired laboratory instruments used to validate FDA regulated products. In 1992, I was promoted to a new position where I modified, designed, and fabricated new custom instruments to validate the quality and safety of products for the corporation.

7. In 1996, I began to manage a small team that worked on the design, manufacture, and global distribution of unique custom instruments that are employed to validate a wide variety of products being manufactured throughout Kimberly-Clark's global manufacturing facilities (by 2011, the number of apparatuses and instruments used to validate operations at Kimberly-Clark's global manufacturing facilities had grown to over 750 instruments).

8. Around the middle of 2006 or early 2007, I was moved to Corporate Quality and my duties shifted from designing custom instruments to overseeing mass production and global distribution of custom instruments. I continued to manage the inventory of custom instruments used to validate and calibrate Kimberly-Clark's manufacturing processes until November 2, 2011.

9. I was recognized three times on Kimberly-Clark intranet home page, twice for cost savings and once for team accomplishment.

EXPERT QUALIFICATIONS

10. DEGREES AND CERTIFICATES

a. Metal Fabrication and Welding Certificate – 1984 – Fox Valley Technical College

b. Associated Degree in Electronics Technology –1989 – Fox Valley Technical College

c. Project Management Certificate – 2007 – Milwaukee School of Engineering

d. Bachelors in Business (emphasis on operations) – 2012 – Milwaukee School of Engineering

e. Lean Enterprise Project Certificate - 2013 - Fox Valley Technical College

f. Project Management Certificate - 2007 - Milwaukee School of Engineering

11. WORK EXPERIENCE (at Kimberly-Clark)

a. Building Maintenance Technician from approximately 1/30/1989 to 05/01/1991, when I maintained building HVAC, security systems, and maintained testing instruments used to test products such as diapers, Feminine Care Products (FDA-regulated), etc.

b. Electrical Engineering Technician from approximately 05/01/1991 to 01/01/1993, when I applied electronic controls to custom converting equipment for Kimberly-Clark Jenks converting mill.

c. Scientist 1 and Quality Specialist II from approximately 01/01/1993 to 11/2/2011. In this position, I designed and fabricated custom instruments used to validate both raw materials and finished products, such as Huggies diapers, feminine care products, adult care products, surgical gowns, etc. After the instrument concept was developed, the drawings were finalized. The drawings were then sent to vendors to replicate the custom instrument. The vendors would then send these instruments to Kimberly-Clark Central Stores. From there, they were distributed globally.

12. PATENTS (first five are directly related to garment-like products such as diapers and feminine care products)

a) Mannequin System - Patent Date - May 11, 2010 - Patent Number US 7712640

b) Mannequin with More Skin-like Properties - Patent Date - June 23, 2009 - Patent Number US 7,549,866

c) Improved Mannequin System - Patent Date - January 12, 2005 - Patent Number US 7,712,640

d) Virtual Arm for Measurement of Humidity, Temperature, and Water Vapor Transmission Rate in Materials - Patent Date - December 20, 2002 – Patent Number US 7,037,112

e) Method and Apparatus of Detecting Pooling of Fluid in Disposable or Non-Disposable Absorbent Articles - Patent Date - August 30, 2002 - Patent Number US 7,174,774

f) Spindle System, Apparatus, and Methods for Applying Spindle Apparatus - Patent Date - August 1, 2006 – Patent US 7,590,467

g) Spindle System, Apparatus, and Methods for Applying Spindle Apparatus - Patent Date - May 17, 2005 - patent number US 6,895,296

13. PUBLICATIONS

a) ET Tube with Multiple Cuff Chambers - Publication Date February 5, 2009

b) Single-Use Portable Hand Wash Sanitizer - Publication Date November 21, 2005

c) User-Friendly High Capacity Jaw for Evaluating Materials - Publication Date September 6, 2005

d) Cradle Tracer Gas System for Testing Breathability Publication Date January 6, 2005

KIMBERLY-CLARK'S PRACTICES

14. During my career at Kimberly-Clark, I received FDA training and became very familiar with FDA regulations. This training alongside my education and experience led me to conclude that Kimberly-Clark was consistently and knowingly noncompliant with FDA regulations and that senior management was consciously indifferent to the safety of a wide range of products—both regulated and unregulated by the FDA. My protests in response to this led to a series of conflicts that culminated in my termination in 2011, once the company realized that I would not follow the leadership and let sleeping dogs lie, as discussed below.

15. On the basis of my experience at Kimberly-Clark, in the manufacturing of both FDA-regulated and non-FDA-regulated, products, I can confidently conclude that the reason Huggies diapers frequently cause severe burns and rashes for their wearers is Kimberly-Clark's failure to adequately regulate the amount of Ahcovel that Kimberly-Clark's production machinery dispenses on Huggies diapers.

16. Ahcovel is a chemical additive employed in a wide range of Kimberly-Clark products, including but not limited to Depends, Poise, Kotex, surgical masks, and Huggies diapers. The use of Ahcovel is clearly noted on page 4 of Kimberly-Clark's patent for "improved fastening systems," which is employed in all Kimberly-Clark diaper products. *See* **Exhibit A**. Ahcovel is applied in Huggies and other products where the surface comes in contact with human skin. Its

purpose of is to facilitate the transfer of urine (in the case of diapers) or blood (in the case of feminine care pads) to the absorbent core of the product. Without it, an infant's urine might not pass through the outer lining of a diaper so as to be absorbed by the core material underneath it, thus leaving the infant wet. It is therefore critical to apply the correct amount of Ahcovel to products and regularly test the machines that dispense Ahcovel to ensure that they are doing this. Apply too little Ahcovel and it will not be effective. Apply too much and it can cause irritation, burns, and other serious injuries to users.

17. Kimberly-Clark's readily acknowledges Ahcovel's dangers in a number of internal documents. For example, sections 3 and 4 of the company's "Safety Data Sheet" for its "Absorbent Core Composite" (composed of Ahcovel and another chemical additive, Glucopon) acknowledge that the Composite can cause eye irritation, respiratory irritation, which can in turn cause lung injury with reduced pulmonary function. Section 4 instructs users to wash thoroughly with soap and water after handling Kimberly-Clark's Ahcoval-laden Absorbent Core Composite and to obtain medical attention if irritation persists. Section 11 acknowledges that Ahcovel is a skin irritant. **Exhibit B**, Kimberly-Clark Safety Date Sheet.[2]

18. The dangerousness of Ahcovel is also acknowledged in the company's "Standard Test Method (STM) EQ-STM-4210/1." As explained in § 1.1, the method's purpose is "to determine the amount of Ahcovel added to coform used in Feminine Care products." Section 1.3 acknowledges that Ahcovel is a skin irritant, stating: "When Ahcovel add-on is too high, skin irritation issues may develop. Add-on that is too low will render the coform non-functional." **Exhibit C**. The Standard Test Method employed for Huggies diapers is similar.

[2] Highlighting in the exhibits is my own.

19. Responding to consumer concerns about the safety of Huggies, Kimberly-Clark has stated:

> All of our products must pass stringent safety reviews prior to making it to retailer shelf. *This review includes the superabsorbent material in question* which has been thoroughly evaluated by more than 450 medical and scientific studies and has been used safely for years in our HUGGIES products and across the diaper industry.

Exhibit D

20. However, Kimberly-Clark is here misdirecting consumers from the true source of the skin irritation. The cause of the burns and rashes produced by Huggies is not the "superabsorbent materials"—the materials urine is ultimately absorbed into—but the Ahcovel that makes urine absorbable in the first place. The skin of Huggies wearers does not normally come into contact with polyacrylate absorbents. But it does come into contact with Ahcovel, which is applied on the outer lining and allows urine to penetrate that lining in order to reach the absorbents. Polyacrylate absorbents are used across all diaper brands, but Ahcovel is proprietary to Kimberly-Clark, and that is what explains the disproportionate number of complaints about Huggies and other Kimberly-Clark brand names.

21. These complaints arise because Kimberly-Clark consistently fails to properly maintain, calibrate, and validate the machinery that produces its various products. In the context of Huggies and other products requiring Ahcovel, this means that Kimberly-Clark cannot ensure that the proper quantity of the chemical is being dispensed. During my time working for Kimberly-Clark, I saw that when a new instrument was designed or an existing instrument was modified, no validation was undertaken to ensure that the instrument would function as designed and intended. The company would make ad hoc changes to the instruments without evaluating the effect of the change through an established testing protocol.

22. For example, at one point, Kimberly-Clark paid Integrated Paper Services, a contract product testing company, to create manuals for instruments without providing Integrated with any information about instrument design and performance specification. As a result, the manuals were useless and could not be used to properly test those instruments. This was to be expected, given Kimberly-Clark's consistent indifference to these things.

23. As part of my job responsibilities, I performed on-site quality assurance inspections at the Conway, Arkansas facility that manufactures feminine care tampons and pads. During one of my inspections, I discovered that Kimberly-Clark's quality testing procedures violated numerous FDA regulations. The instrumentation used was in poor shape and was being handled by ill-trained employees, so it could not be used to validate the products being manufactured. On October 26, 2011, I sent a letter to my superiors regarding these violations.

24. I know that Kimberly-Clark fails to properly calibrate the machinery on its production lines not only from personal experience but also from Kimberly-Clark's own internal documents. For example, the Standard Test Method referenced above, *see* **Exhibit C**, betrays Kimberly-Clark's knowing indifference to testing and calibrating the machinery that makes its products. The "Reason for Change" box on page 12 states "Verification and Calibration section, and research references have been removed." With these items removed, there is no means of testing whether manufacturing equipment is properly calibrated—and hence whether the correct amount of Ahcovel is being dispensed on Huggies diapers and other Kimberly-Clark products designed to absorb fluids.

25. Kimberly-Clark's "Quality Management Assessing Rating Tool" (QMART), *see* **Exhibit E**, reveals the same reckless indifference to maintaining and testing the production lines that produce Huggies and dispense Ahcovel. The second to last page discloses that the "testing

column" was hidden on Version 8 of the document on June 15, 2010. The removal of this testing column substantially handicapped Kimberly-Clark's quality control system because it eliminated vital quality-control feedback. As a result, products being manufactured can vary greatly from the design specifications—including with respect to the amount of Ahcovel that should be dispensed on Huggies and other Kimberly-Clark products (such as feminine care pads).

26. This reckless indifference to consumer safety is confirmed by Kimberly-Clark's own internal audits. Attached to this Declaration as **Exhibit F** is a reproduction of Kimberly-Clark's December 10, 2010 "Compliance Testing Facility CTF Audit," which highlights the dereliction described above. The Audit observes that:

a. "Internal assessments are not being performed per the established procedure. Specifically, the walk-through inspections that are to supplement the comprehensive audits are not being performed approximately every three months as prescribed by procedure CT-PR-000871" (Minor NC No. 5)

b. "Equipment calibration and maintenance is not being managed in a manner to ensure accurate performance" (Minor NC No. 5)

c. "Concerns related to precision and validation were raised during the audit of STM [standard test method] management" (audit follow-up)

27. Diapers are not regulated by the FDA, so Huggies have not received the same FDA scrutiny as have some other product lines. However, FDA inspections made in connection with FDA-regulated Kimberly-Clark products that also rely on Ahcovel reveal the same problems that plague Huggies and that account for the frequently excessive Ahcovel that is dispensed on Huggies. In every case, the problem is Kimberly-Clark's failure to properly maintain its production

machinery so as to ensure that the appropriate amount of a potentially dangerous chemical is applied to products.

28. This is again showed by the FDA's Warning Letter, dated March 9, 2001, to Wayne Sanders, the CEO of Kimberly-Clark at that time. *See* **Exhibit G**. The letter observes the following:

a. "Management reviews of the quality system are not effective in that all quality data is not analyzed, documented and trended as required by 21 CFR820.20."

b. "Failure to establish and maintain procedures for rework, to include re-testing and re-evaluation of nonconforming products after rework to ensure the product meets its current approved specifications as required by 21 CFR820.90(b)(2)."

c. "Failure to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(c)."

29. The March 9, 2001, letter also observes that "[t]he specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system." **Exhibit G** (emphasis added).

30. The above problems were never corrected and were indeed noted again in the FDA's June 2012 citation to Kimberly-Clark's Neenah, Wisconsin facility, attached hereto as **Exhibit H**, which observed in pertinent part:

a. "Design validation did not ensure the device conforms to defined user needs and intended uses." (Observation 1)

b. "The design was not validated under defined operating conditions and using initial production units, lots or batches or their equivalents." (Observation 2)

c. "Your document, *Personal Care Supplier Quality System Requirements Document, ST-00017* states that component manufacturers, 'Must implement sufficient controls to comply with the specification.' [H]owever, sufficient controls have not been defined and controls that must be implemented to comply with specifications have not been communicated to contract manufacturers."

31. Kimberly-Clark's reckless indifference to the proper dispensing of Ahcovel is also betrayed by the numerous FDA MAUDE injury reports that have been filed in connection with products that rely on Ahcovel. Since diapers are not regulated by the FDA, there are no FDA MAUDE reports about Huggies specifically. But the basic cross-product and company-wide problem is revealed again and again by the injuries caused by other Ahcovel-reliant personal care products manufactured by Kimberly-Clark that, being FDA-regulated, are documented in MAUDE reports. For example, one purchaser of Kimberly-Clark's Poise Liners garment (protective for incontinence) complained of "[s]everal days of burning and discomfort followed by severe peripheral pain landing me in the hospital." **Exhibit I**. A consumer of the Goodnites Garments (also for incontinence) complained that "her daughter developed a rash with two abscesses that need to be drained and resulted in hospitalization." **Exhibit J**. And a purchaser of Kotex Natural Balance Pantiliners complained that she had "a skin reaction including fusing of the skin of the genitals, an abnormal, progressive scar-like condition." **Exhibit K**.

32. A longer list of injuries arising from the use of Kimberly-Clark products with Ahcovel is attached as **Exhibit L**. They contain the same patterns of injury that have been known to plague Huggies diapers, showing that improperly regulated Ahcovel is the common cause.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 22, 2022

By: Frank Fritz Kromenaker