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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,)
) VOLUME 1
Plaintiff,)
) C.A. No. 20-365 (MN)
v.)
)
ETON PHARMACEUTICALS, INC.,)
)
Defendant.)

Monday, March 14, 2022
08:45 a.m.
Bench Trial

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE MARYELLEN NOREIKA
United States District Court Judge

APPEARANCES:

FISH & RICHARDSON
BY: CORRIN N. DRAKULICH, ESQ.
BY: CHRISTINA D. BROWN-MARSHALL, ESQ.
BY: DOUG McCANN, ESQ.
BY: DEXTER WHITLEY, ESQ.
BY: ELIZABETH FLANGAN, ESQ.

Counsel for the Plaintiff

DEVLIN LAW FIRM
BY: TIMOTHY DEVLIN, ESQ.
BY: NEIL A. BENCHELL, ESQ.

Counsel for the Defendant

Kuhn - direct

10:33:59 1 Your Honor, we appreciate the Court's time and
10:34:02 2 attention. We look forward to bringing this case. Thank
10:34:05 3 you.

10:34:05 4 THE COURT: Let's take a quick break before our
10:34:08 5 first witness. Fifteen minutes.

10:34:10 6 COURT CLERK: All rise.

10:34:11 7 (A brief recess was taken.)

10:50:54 8 THE COURT: All right. Please be seated.

10:50:58 9 MS. DRAKULICH: Plaintiff calls as its first
10:51:00 10 witness, Dr. Robert Kuhn.

10:51:02 11 COURT CLERK: Please raise your right hand.
10:51:04 12 Please state and spell your full name for the record.

10:51:07 13 THE WITNESS: Robert Kuhn. K-U-H-N.

10:51:11 14 ROBERT KUHN, having been duly sworn was examined
10:51:17 15 and testified as follows:

10:51:19 16 THE COURT: Good morning.

10:51:21 17 THE WITNESS: Good morning.

10:51:21 18 MS. BROWN-MARSHALL: Good morning, Your Honor.
10:51:23 19 Christina Brown-Marshall on behalf of the Exela Pharma
10:51:25 20 Sciences.

10:51:26 21 DIRECT EXAMINATION

10:51:27 22 BY MS. BROWN-MARSHALL:

10:51:30 23 Q. Good morning, Dr. Kuhn.

10:51:31 24 A. Good morning.

10:51:32 25 Q. Would you please tell us what you do for a living?

10:51:34 1 A. I am a pediatric clinical pharmacist at the Kentucky
10:51:38 2 Childrens Hospital at the University of Kentucky and a
10:51:41 3 professor of pharmacy at the Kentucky University College of
10:51:45 4 Pharmacy.

10:51:45 5 Q. What is a pediatric clinical pharmacist?

10:51:47 6 A. Pediatric clinical pharmacist is a pharmacist who
10:51:50 7 works primarily in a children's hospital or children's
10:51:54 8 clinic with the physicians, nurses and patients, we select
10:51:58 9 drugs, monitor drugs, oversee the preparation of drugs and
10:52:01 10 help educate parents and children about medications.

10:52:05 11 Q. And how long have you been a practicing clinical
10:52:08 12 pediatric pharmacist?

10:52:11 13 A. Almost thirty-eight years.

10:52:11 14 Q. And what training have you had in the field?

10:52:14 15 A. I received my bachelor in pharmacy from Ohio State in
10:52:18 16 1980 and worked as a pharmacist in a hospital for almost two
10:52:21 17 years, went back and got my doctorate of pharmacy and
10:52:24 18 residency at the University of Texas, finished that program
10:52:28 19 in 1984, and then did a pediatric pharma fellowship at
10:52:31 20 Nationwide Children's Hospital in Columbus until July 1985
10:52:34 21 when I joined the faculty of UK.

10:52:42 22 Q. In your role as a practicing pediatric clinical
10:52:45 23 pharmacist, are you involved with what we heard referred to
10:52:48 24 as total parenteral nutrition?

10:52:51 25 A. Yes.

10:52:52 1 Q. What is total parenteral nutrition?

10:52:54 2 A. Total parenteral nutrition is applying by IV
10:52:58 3 nutrition to a particular patient, children who would need
10:53:02 4 and who cannot take it for one reason or another, so all the
10:53:05 5 nutrients, the electrolytes and all those things are put in
10:53:09 6 IV solutions and then infused in the child to provide the
10:53:13 7 nutrition they need.

10:53:14 8 Q. And is total parenteral nutrition also referred to as
10:53:21 9 TPN for short?

10:53:21 10 A. That's common.

10:53:21 11 Q. You mentioned earlier that you teach at the
10:53:25 12 University of Kentucky. Do you teach about TPN?

10:53:27 13 A. Yes, I do. I teach in pharmacy school. We have a
10:53:31 14 pediatric elective course, we go into great detail about
10:53:35 15 some of the formulation issues and stuff. In addition our
10:53:38 16 residents, pediatric pharmacy residents are house staffed in
10:53:41 17 pediatrics. And our students, we educate them about TPN and
10:53:44 18 all the processes we use.

10:53:50 19 Q. Do you also perform research at the University of
10:53:54 20 Kentucky?

10:53:54 21 A. Yes, I do.

10:53:54 22 Q. In what areas?

10:53:55 23 A. Primarily in pediatric drug therapy and specializing
10:54:00 24 in pediatric pulmonary drug delivery, cystic fibrosis and
10:54:05 25 then a fair amount of work in looking at aluminum deposition

10:54:11 1 or contamination of TPN solutions.

10:54:14 2 Q. And how did you get interested in doing research in
10:54:17 3 aluminum and TPN compositions?

10:54:20 4 A. Well, certainly it is part and parcel of a pediatric
10:54:25 5 pharmacist's job to oversee the preparation of TPN. I was
10:54:29 6 working with our neonatal unit, and we noticed that despite
10:54:33 7 giving adequate calories and vitamin D that many of our
10:54:36 8 children were developing changes in bone. Our
10:54:39 9 neonatologists were somewhat stumped by this, even though
10:54:43 10 they were giving adequate amounts of calcium and phosphorus
10:54:48 11 and vitamin D. So we started looking and saying what are
10:54:52 12 the potential reasons for this. This is the United States
10:54:54 13 of America. This should not be happening, this is
10:55:01 14 osteopenia, this osteomalacia we're seeing in these bones
10:55:02 15 are troublesome in these newborns because obviously they're
10:55:04 16 just a few weeks old.

10:55:07 17 Q. Was your research in aluminum and TPN ever published?

10:55:11 18 A. Yes.

10:55:11 19 Q. Dr. Kuhn, I'm showing you PDX 302. Is this the paper
10:55:14 20 you had in mind?

10:55:17 21 A. Yes, it is.

10:55:17 22 Q. And Dr. Kuhn, do you consider yourself to be an
10:55:20 23 expert in clinical pharmacies?

10:55:22 24 A. Yes, I do.

10:55:23 25 Q. Do you consider yourself to be an expert in the area

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10:55:25 1 of total parenteral nutrition?

10:55:28 2 A. I would say so.

10:55:30 3 MS. BROWN-MARSHALL: Your Honor, we would like
10:55:31 4 to offer Dr. Kuhn as an expert in pharmacy and total
10:55:35 5 parenteral nutrition.

10:55:35 6 MR. DEVLIN: No objection, Your Honor.

10:55:35 7 THE COURT: All right. He will be so
10:55:38 8 recognized.

10:55:38 9 BY MS. BROWN-MARSHALL:

10:55:39 10 Q. Dr. Kuhn, you understand this case is related
10:55:41 11 specifically to cysteine products used in TPN solutions,
10:55:45 12 right?

10:55:45 13 A. Yes, I am.

10:55:46 14 Q. What kind of patients receive TPN?

10:55:49 15 A. Well, primarily TPN in the children's hospital was
10:55:53 16 focused primarily on premature infants and in children who
10:55:57 17 cannot -- who we can't use their gut to give them the
10:56:00 18 calories they need. Certainly the biggest part of those are
10:56:03 19 premature babies in the neonatal intensive care units across
10:56:06 20 the country. So across the board we use TPN to supplement
10:56:10 21 or actually provide all the calories they need and also
10:56:13 22 manage their electrolytes and fluids as well.

10:56:20 23 Q. Approximately how many neonatal patients receive TPN
10:56:24 24 on a given day in the U.S.?

10:56:25 25 A. I think conservatively 4,000, and probably in the

neighbor of five or 6,000. Obviously we have some variation depending on the number of premature births, but it's in the thousands per day.

Q. You use the term neonate. What is a neonate?

A. Neonate by definition is a child born in the first -- a child who is less than thirty days old, post neonate.

Q. Why would a neonatal patient need to receive TPN?

A. Because they basically have no caloric reserve. If you take a term baby who weighs seven or eight pounds, they have a certain amount of caloric reserve they could use if indeed they're very sick. It's not long, but a premature baby who weighs 700 grams or 800 grams has virtually no caloric reserve, so we have to implement supplemental or parenteral nutrition very early on, usually within the first day of life.

Q. Do neonatal patients in general receive any special consideration with respect to TPN?

A. They certainly do. First they require a lot more protein than we do, in the neighborhood of three-and-a-half to four grams per kilo which is at least twice if not three times what we require as adults. They also have a huge requirement of calcium and phosphorous because they're trying to lay down this bone that would normally occur in utero. And they also can't make certain amino acids, at least their ability to make amino acids is diminished so

10:58:01 1 sometimes we have to add special formulations of amino acids
10:58:03 2 including the cysteine to add these babies. In addition
10:58:06 3 we're doing all this in typically three or four ounces of
10:58:10 4 solution.

10:58:11 5 Q. And do neonatal patients present any special risks
10:58:15 6 with respect to TPN?

10:58:17 7 A. Well, certainly a child who weighs seven or
10:58:20 8 800 grams, any time a potential toxin would be introduced a
10:58:25 9 potential risks is great because it's so small. And often
10:58:28 10 it has something to do about the elimination of the kidneys,
10:58:31 11 the kidneys are not well developed. In utero, your mom
10:58:34 12 clears many of the things the child makes as waste, but when
10:58:37 13 a child is born then they have to take that over.

10:58:40 14 Q. And Dr. Kuhn, how are TPN solutions prepared?

10:58:43 15 A. Well, it's a complex process, so they're individually
10:58:46 16 compounded or admixed every day. Once the team, and I have
10:58:49 17 often been on the teams to actually look at their
10:58:52 18 electrolyte values, their fluid requirement, the amount of
10:59:05 19 amino acids they need, the dextrose, and that formulation is
10:59:08 20 put into an order, it's then processed by two different
10:59:11 21 pharmacists, checked for compatibility, solubility and
10:59:14 22 transferred electronically to our class 10,000 room, our IV
10:59:17 23 clean room and the technicians prepare that with an
10:59:20 24 automated device. And it's checked again by a pharmacist
10:59:23 25 who visually inspects it and sent back up to the units for

10:59:30 1 administration by the nurses.

10:59:31 2 Q. And Dr. Kuhn, you used the term admix, what does
10:59:34 3 admix mean?

10:59:35 4 A. Admixture is simply taking more than one ingredient
10:59:39 5 and mixing them together primarily in parenteral solution or
10:59:43 6 parenteral IV, so admixing, in this case there is a lot more
10:59:47 7 than one or two.

10:59:48 8 Q. Dr. Kuhn, have you prepared a demonstrative that
10:59:50 9 shows how TPN solutions are prepared and administered?

10:59:54 10 A. Yes, I have.

10:59:55 11 Q. And Dr. Kuhn, what are you showing in this animation?

10:59:58 12 A. Well, we start with an amino acid so we would choose
11:00:04 13 a specific formulation of amino acid. In addition we would
11:00:08 14 add L-cysteine because it's incompatible with the long-term
11:00:14 15 storage of these amino acids. We then would add a dextrose
11:00:17 16 or sugar carbohydrate source and determine what that needs
11:00:21 17 to be. And we then have a manifold or list of electrolytes
11:00:25 18 including calcium phosphorous and a lot of other
11:00:28 19 electrolytes. And subsequently we have trace elements
11:00:31 20 because there are certain trace elements that we all get
11:00:34 21 normally through nutrition that we require; pediatric
11:00:38 22 multivitamins which are more geared specifically for their
11:00:42 23 vitamin needs, and then we use water for injection to allow
11:00:46 24 for the proper mixing and clearing of the different lines
11:00:50 25 because we put all this in a sterile manifold. Then those

11:00:57 1 are pumped along with a separate bag for lipids or fat, we
11:01:02 2 all like fat, right, and then those are put together in a
11:01:06 3 compounder and all those channels are then put together and
11:01:09 4 infused or pumped into a single IV bag denoted on the left.
11:01:16 5 And on the right we use that for the lipids since they are
11:01:20 6 often incompatible to put those together.

11:01:24 7 So our bag on the left so to speak and our bag
11:01:28 8 on the right is then visually inspected, labeled, bar coded
11:01:32 9 and then sent to a neonatal care unit. This would be one of
11:01:37 10 our patients, a larger patient. And those would be
11:01:39 11 connected by the umbilical veinous line which is the
11:01:45 12 umbilical spot that we use to put a catheter in, so the
11:01:49 13 belly button if you want to use the colloquialism. So we
11:01:54 14 use that to infuse centrally both the TPN and the lipids.

11:01:59 15 Q. You mentioned cysteine is one of the components
11:02:01 16 that's in that solution for the neonatal solutions. What is
11:02:06 17 a cysteine?

11:02:07 18 A. Cysteine is an amino acid that is necessary for the
11:02:10 19 growth and development of everyone. Now, typically adult
11:02:14 20 and older children actually make or convert it, but we have
11:02:19 21 good reason to believe that a premature baby, they don't
11:02:22 22 have the enzyme activity to do that.

11:02:24 23 Q. And does cysteine provide any additional benefits
11:02:28 24 when it's incorporated into a TPN solution?

11:02:32 25 A. Well, I hope you can see that this is very much a

11:02:34 1 solubility issue. We're fortunate enough that L-cysteine
11:02:38 2 has a low enough pH it drops the pH of overall solution and
11:02:42 3 we're able to maximize our calcium and phosphorus which
11:02:48 4 allows us to deliver that to the infant. Without that, we
11:02:50 5 would have to limit the amount of calcium and phosphorous we
11:02:54 6 would have to put in this TPN. As I said before, those are
11:02:58 7 two essential things that are needed in very high amounts.
11:03:01 8 For instance, a 28 weeker, 50 percent of their ribs is still
11:03:08 9 cartilage, unlike a term baby it's more like 80 percent. So
11:03:12 10 even just looking at the rib cage for example there is a
11:03:15 11 tremendous amount of matriculated bone that has to be made.

11:03:18 12 Q. You mentioned that one of the risks to avoid in
11:03:21 13 providing TPN to a neonatal patient is to expose them to the
11:03:24 14 least amount of potential toxins, right?

11:03:27 15 A. Absolutely.

11:03:29 16 Q. Is aluminum one of those potential toxins?

11:03:32 17 A. Unfortunately yes.

11:03:35 18 Q. What are the side effects of aluminum toxicity?

11:03:38 19 A. Well, there is two that certainly have been well
11:03:41 20 documented in the literature, neurotoxicity or changes in
11:03:44 21 neuro development over time, and as I mentioned before,
11:03:47 22 changes in deposition of aluminum to bone that leads to
11:03:50 23 weaker bones and potential problems down the road.

11:03:53 24 We also think it's very important to oxidative
11:03:56 25 metabolism. These children have very high metabolic rates.

11:04:02 1 They need a hundred calories per kilo. Typically the adult
11:04:07 2 male and female needs between 18 and 20. They have these
11:04:10 3 high caloric requirements so they need all these additional
11:04:14 4 items to make sure that they can synthesize the amino acids
11:04:19 5 and produce proteins that are required. There is some
11:04:22 6 evidence perhaps anemia may be part of that as well with the
11:04:26 7 aluminum displacing iron, so there are a number of factors
11:04:29 8 that really point us to try to minimize exposure to
11:04:33 9 aluminum.

11:04:33 10 And finally the only way the human body can get
11:04:36 11 rid of aluminum is through the kidney. As I mentioned
11:04:40 12 before, the kidney function of these premature babies is
11:04:43 13 quite diminished. It's normal for them because of the in
11:04:46 14 utero, but because of premature it's greatly reduced. Their
11:04:50 15 kidneys cannot perform at the level ours can.

11:04:55 16 Q. If aluminum is so bad, why is it in the TPN solution
11:05:00 17 at all?

11:05:02 18 A. Well, because it's a contaminant of some of the
11:05:06 19 product that we use in preparing the solutions. And
11:05:10 20 specifically L-cysteine, the calcium salts and the phosphate
11:05:14 21 salts are at least three of the biggest offenders of those
11:05:18 22 aluminum compositions.

11:05:22 23 Q. And why is aluminum toxicity such a risk for TPN
11:05:26 24 patients?

11:05:29 25 A. Well, the human body does a fantastic job when we

11:05:33 1 consume aluminum through the gut. There is many mechanisms
11:05:38 2 that prevent the absorption of aluminum. When we get it IV,
11:05:43 3 those protections are gone, whatever aluminum the patient
11:05:46 4 gets other than what they can eliminate renally it stays in
11:05:50 5 the body.

11:05:50 6 Q. Are there any treatments available for TPN patients
11:05:54 7 who have been exposed to aluminum?

11:05:56 8 A. To my knowledge there is no effective treatment to
11:05:59 9 treat aluminum loading in any patient including a neonate.

11:06:02 10 Q. In your experience, how long has aluminum toxicity
11:06:05 11 been an issue in the field of TPN?

11:06:07 12 A. It was first identified in the mid 1980's. And it's
11:06:12 13 been a constant concern of neonatologists, pharmacists and
11:06:17 14 health care professionals since.

11:06:19 15 Q. Have you prepared a demonstrative to show the
11:06:22 16 awareness of aluminum toxicity in TPN?

11:06:25 17 A. Yes, I have.

11:06:26 18 Q. And I'm showing you PDX 304. Is this that
11:06:31 19 demonstrative?

11:06:32 20 A. Yes. Yes, it is.

11:06:32 21 Q. And with reference to PDX 304, let's start with the
11:06:32 22 first entry which is Sedman.

11:06:42 23 Dr. Kuhn, I would like you to turn to exhibit
11:06:42 24 PTX 190 in your binder.

11:06:50 25 A. Yes, I found it.

11:06:51 1 Q. Dr. Kuhn, is this a 1984 article by Sedman titled
11:06:56 2 Evidence of Aluminum Loading in Infants Receiving
11:06:58 3 Intravenous Therapy that you considered in the course of
11:07:02 4 forming your opinions in this case?

11:07:04 5 A. Yes, it is. I believe actually it was 1985. I
11:07:07 6 believe you said 1984.

11:07:08 7 Q. Thank you. 1985.

11:07:10 8 Dr. Kuhn, I'm showing you PDX 305 which is an
11:07:14 9 excerpt of Sedman page 1. What does Sedman observe in this
11:07:19 10 article?

11:07:19 11 A. Well, this was one of the first papers that
11:07:22 12 identified aluminum loading in infants that received IV
11:07:27 13 nutrition, parenteral nutrition versus those that didn't.
11:07:31 14 Back in 1980, it was a relatively new procedure. They
11:07:35 15 looked at what do we see in these babies who get the TPN?
11:07:40 16 Where did the aluminum go? How much is there? How much
11:07:43 17 deposits into the bone? How much is renally eliminated?
11:07:47 18 Are there plasma levels or serum levels to help us
11:07:52 19 understand if this process is real?

11:07:54 20 Q. I'm now showing PDX 306 which is two excerpts from
11:07:59 21 Sedman, pages 5 and 6. Dr. Kuhn, what have you highlighted
11:08:04 22 on this slide?

11:08:05 23 A. Well, on panel A you can see that the gray bar shows
11:08:09 24 the amount of plasma aluminum that's actually in the group
11:08:14 25 that received TPN. And the normal infants would be the

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11:08:17 1 white bar. You can see the dramatic increase in plasma, so
11:08:22 2 there is evidence that it's in the plasma or the blood. The
11:08:26 3 urinary creatine ratio which is B shows that there is a much
11:08:32 4 larger elimination of aluminum which makes sense, but even
11:08:36 5 more so in Figure 3, you see accumulation of bone,
11:08:40 6 accumulation of aluminum in the bone, pardon me, and
11:08:43 7 unfortunately these are samples from autopsies and
11:08:49 8 necropsies of patients who did not survive their neonatal
11:08:54 9 course.

11:08:54 10 So it's demonstrated I think for the first time
11:08:57 11 in neonates that aluminum deposited into the bone that
11:09:01 12 certainly was -- there was an aluminum loading going on
11:09:04 13 because it was in the plasma or the blood and that also even
11:09:08 14 though there was urinary excretion of it, it's still
11:09:12 15 deposited.

11:09:12 16 Q. And Dr. Kuhn, what was the significance of the Sedman
11:09:16 17 article?

11:09:16 18 A. I think it was the first evidence for neonatologists
11:09:21 19 and pharmacists and all the health care professionals that
11:09:25 20 this is a real problem, that we have to think about how we
11:09:28 21 can address this because it's evident in just these children
11:09:31 22 who got TPN.

11:09:32 23 Q. Mr. Doyle, I would like to call up PDX 304, please.

11:09:40 24 Dr. Kuhn, referring back to your timeline, let's
11:09:44 25 talk about the next entry which is a 1986 FDA workshop. If

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11:09:49 1 you would, please, turn to PTX 171 in your binder.

11:09:56 2 A. Yes, I have got it.

11:09:57 3 Q. Dr. Kuhn, is this a transcript of a 1986 FDA workshop
11:10:01 4 on aluminum in total parenteral nutrition products that you
11:10:07 5 considered in the course of forming your opinions in this
11:10:09 6 case?

11:10:09 7 A. Yes, it is.

11:10:13 8 Q. Dr. Kuhn, I'm showing you PDX 307 which contains
11:10:17 9 excerpts from the FDA workshop transcript at page 1. Had
11:10:21 10 you seen this document prior to your work on this case?

11:10:25 11 A. A long time ago, yes.

11:10:26 12 Q. Approximately when?

11:10:29 13 A. Early 1987.

11:10:31 14 Q. And why were you looking at this document in 1987?

11:10:35 15 A. Well, as I mentioned before, in 1985, we made these
11:10:40 16 observations in our unit. Other people were making
11:10:43 17 observations when the Sedman paper came out. I think there
11:10:47 18 was a wake up call to both clinicians and the industry and
11:10:51 19 the FDA to say we got to do something about this. So they
11:10:54 20 held this workshop, which was open to the public and the
11:10:58 21 experts to come in and say let's brainstorm, how can we
11:11:02 22 eliminate aluminum from these parenteral products for
11:11:05 23 everybody, not just neonates, but for everybody.

11:11:08 24 Q. What was the takeaway in the field from this
11:11:12 25 workshop?

11:11:11 1 A. Well, a lot of work needed to be done. And currently
11:11:15 2 we really didn't have labeling on many of the products about
11:11:19 3 how much aluminum they contain, so I don't read minds very
11:11:23 4 well, so it would be nice to know how much aluminum is in
11:11:28 5 these products, and also look at what are the major
11:11:30 6 offenders. And working with industry what are some
11:11:33 7 standards or possible solutions we might use and even to
11:11:36 8 sort of how far do we assay this. Aluminum contamination
11:11:41 9 can occur in samples for very easy reasons, not just an easy
11:11:47 10 analytical issue, let's put our heads together and see what
11:11:50 11 we can do is my interpretation.

11:11:52 12 Q. And Dr. Kuhn, I'm showing you PDX 308 which is an
11:11:56 13 excerpt of page 132 of the FDA workshop transcript. Was
11:12:00 14 aluminum contamination specifically of the cysteine
11:12:04 15 component of TPN discussed at this workshop?

11:12:10 16 A. Yes, it was identified as an important component in
11:12:13 17 this contamination.

11:12:15 18 Q. Mr. Doyle, I would like to go back to PDX 304.
11:12:21 19 Dr. Kuhn, let's go on to the next entry which is Klein. I
11:12:30 20 would like to turn to PTX 162 in your binder.

11:12:32 21 A. Yes, I found it.

11:12:34 22 Q. Dr. Kuhn, is this a 1989 article by Klein titled
11:12:38 23 Hypocalcemia Complicating Deferoxamine Therapy in an Infant
11:12:42 24 with Parenteral Nutrition-Associated Aluminum Overload:
11:12:45 25 Evidence for a Role of Aluminum in the Bone Disease of

11:12:49 1 **Infants?**

11:12:49 2 A. **Yes, it is.**

11:12:49 3 Q. **Did you consider this document in the course of**
11:12:52 4 **forming your opinions in this case?**

11:12:53 5 A. **Yes, I did.**

11:12:55 6 Q. **Mr. Doyle, I would like to go to PDX 309, please. So**
11:13:01 7 **Dr. Kuhn, I'm showing you PDX 309 which is an excerpt of**
11:13:06 8 **page 1 of the Klein article. First of all, can you please**
11:13:09 9 **translate the title of this article into English so the rest**
11:13:12 10 **of us can understand it?**

11:13:13 11 A. **I will do my best.**

11:13:15 12 **So this was a patient who Dr. Klein in their**
11:13:18 13 **group who as an eight-month infant had demonstrated**
11:13:21 14 **osteopenic bone disease, so this child was only eight-months**
11:13:24 15 **old and had received TPN. They said can we do something**
11:13:27 16 **about this? This showed up in eight months. This is very**
11:13:30 17 **early, even though we made some observations as well. They**
11:13:33 18 **said maybe if we use a short course of deferoxamine which,**
11:13:36 19 **Your Honor, we used to treat iron overload syndromes in**
11:13:39 20 **patients in heart attack, it's a known therapy.**
11:13:42 21 **Unfortunately it didn't really remove a lot of aluminum, but**
11:13:45 22 **caused significant hypercalciuria or low calcium in this**
11:13:48 23 **patient, so that wasn't an effect -- it wasn't a safe enough**
11:13:51 24 **process to work in this child. This is the first case**
11:14:04 25 **report I'm aware of.**

11:14:02 1 Q. You have used the term osteopenia. What is that?

11:14:05 2 A. Osteopenia by definition is just poor formation of
11:14:09 3 bone. Calcium and phosphorous work together and strengthen
11:14:16 4 our bones and that's what really gives us the stability and
11:14:19 5 long-term health of our bones.

11:14:21 6 Q. And was that the same disorder that you observed in
11:14:25 7 your own neonatal unit at the UK Hospital?

11:14:29 8 A. It was consistent with the ones we talked about
11:14:31 9 earlier, yes.

11:14:32 10 Q. In your opinion, what is the significance of the
11:14:35 11 Klein article?

11:14:36 12 A. Well, my opinion is that if this happens, there is
11:14:40 13 not much we can do about it. So what we need to do is try
11:14:43 14 to prevent them from getting it.

11:14:46 15 Q. All right. Mr. Doyle, I would like to go back to PDX
11:14:49 16 304, please.

11:14:50 17 Let's move on to the next entry in your timeline
11:14:53 18 which is the Bishop article. Would you please turn to PTX
11:14:56 19 181 in your binder.

11:15:00 20 A. Yes, I got it.

11:15:02 21 Q. Dr. Kuhn, is this a 1997 article by Bishop titled
11:15:05 22 Aluminum Neurotoxicity in Preterm Infants Receiving
11:15:10 23 Intravenous Feeding Solutions which you considered in the
11:15:13 24 course of forming your opinions in this case?

11:15:16 25 A. Yes, I did.

11:15:18 1 Q. So this article comes eight years after the Klein
11:15:21 2 article, is that right?

11:15:23 3 A. Yes, eight years.

11:15:24 4 Q. Okay. Mr. Doyle, if I could get PDX 310, please.

11:15:30 5 Dr. Kuhn, I'm showing you PDX 310 which is an
11:15:33 6 excerpt of page 1 of the Bishop article. So what sort of
11:15:38 7 study is described in the Bishop article?

11:15:40 8 A. Well, this study of over 200 premature infants who
11:15:46 9 were less than 34 weeks, just to remind you that's at least
11:15:50 10 six weeks premature, who weighed less than 1,850 grams, so
11:15:54 11 in the neighborhood of four pounds, which received either a
11:15:58 12 standard amino acid TPN solution with aluminum in it, or a
11:16:02 13 low or depleted aluminum preparation, they looked at the
11:16:06 14 long-term, the changes in their development over time, over
11:16:10 15 18 months, so sort of standard high dose aluminum and by use
11:16:14 16 the term depleted or low dose aluminum, those two groups.

11:16:20 17 Q. And how did they assess the mental development of
11:16:24 18 those children at 18 months?

11:16:28 19 A. One of the standard methods we do is to look at these
11:16:32 20 infant development scales, and the Bayley Scale of Infant
11:16:36 21 Development is one that's often used by our developmental
11:16:40 22 people and assessment people of how well a child is moving
11:16:44 23 along with their milestones on neurological function, et
11:16:48 24 cetera.

11:16:52 25 Q. And the Bayley score is what was used in the Bishop

11:16:52 1

paper?

11:16:53 2

A. Yes, it was.

11:16:53 3

Q. Are you familiar with the Bayley scale?

11:16:56 4

A. Generally, yes.

11:16:57 5

Q. How does the Bayley scale work?

11:16:59 6

A. Well, it's on a point system so it starts at

11:17:02 7

50 points on the low end, 150 points on the high end, so

11:17:08 8

it's a hundred point increment. Depending on the level of

11:17:11 9

infant development at the very high level where everything

11:17:13 10

is normal, and normal development would be in that very high

11:17:17 11

end of that range in the 150s. And a child with profound

11:17:21 12

lack of infant development or developmental delay would be

11:17:24 13

much in the lower end of that scale, in the 50 plus range,

11:17:32 14

below a hundred for sure.

11:17:34 15

Q. All right. Dr. Kuhn, I'm showing you PDX 311 which

11:17:38 16

is an excerpt of page 2 of the Bishop article. What was the

11:17:41 17

daily aluminum exposure from the standard high aluminum TPN

11:17:45 18

solutions used in the Bishop study?

11:17:47 19

A. It was at 45 micrograms per kilo per day.

11:17:51 20

Q. What was the aluminum exposure from the special

11:17:52 21

depleted aluminum solution in the Bishop study?

11:17:57 22

A. Between 4 to 5 micrograms per kilo per day.

11:18:02 23

Q. Dr. Kuhn, I'm showing you PDX 312 which is an excerpt

11:18:04 24

from page 3 of the Bishop article. What did the experts

11:18:06 25

observe when they compared the Bayley score for the high

aluminum group versus the depleted aluminum group?

A. Using a mental development index which is part of that Bayley score, it was ten points lower in patients who got the higher concentration, the higher exposure to aluminum versus those who did not. And that is statistically significant.

But I think even more important is that the index values of the scale below 85, so that would be between 50 and 85, it was 38 percent in the high aluminum and only 17 percent, so more than a twofold difference. And I think the developmental people and the neonatologists would look at that and say those are children who have significant mental development delay.

Q. Dr. Kuhn, I'm showing you PDX 313 which is an excerpt of page 5 of the Bishop article. What do the authors of the Bishop study conclude from these observations?

A. Two observations, based on the extrapolation of the data from these children that for every day of exposure on average their developmental delay or their index went down one point. I think that that's, you know, taking the group as an aggregate, not that one child made, but taking those 200 some children together, they determined that.

In addition, this really demonstrated the neurotoxic effects of aluminum in this group of children in the United Kingdom. That's the United Kingdom in England,

not the UK I work at. So this long-term sequela certainly is going to be a problem. And this development in our unit, we follow all our babies and especial well baby clinic at 18 months, two years, four years and six years so we can see what kind of development they have. These are the kind of milestones we look to see what kind of success we have or what kind of potential toxicity we have.

Q. You just used the term sequela. What does that mean?

A. Subsequent to, so if you do something what could potentially be down the road. We get the term -- we have all these terms, Your Honor, but sequela, or potential cause and effect.

Q. So overall, what is the significance of the Bishop article?

A. Well, it demonstrates that in this group of children there was significant delay in the development at 18 months. And it was associated with a higher aluminum exposure and for a longer period of time. And finally, that the greatest risk or the greatest notation in loss of development was twofold or more greater than in the low aluminum group.

Q. So other than the significant mental development impairment, did the authors of Bishop do any follow-up studies on aluminum toxicity in the patients?

A. As good neonatologists and physicians in the UK, they followed many of these kids out for fifteen years saying

11:21:29 1 what are the changes we saw, particularly in the bone,
11:21:32 2 because in the first year of life you lay down a lot of
11:21:35 3 bone. In fact, once you become an adolescent you pretty
11:21:39 4 much have your bones for the rest of your life.

11:21:42 5 Q. What did the Bishop authors observe in this 15-year
11:21:47 6 follow up?

11:21:47 7 A. They saw there was about a seven percent reduction in
11:21:50 8 bone mineral content in the spine and the hip which are two
11:21:54 9 easy things to measure in this group that received this high
11:21:59 10 TPN back when they were infants.

11:21:59 11 Q. Mr. Doyle, I would like to pull up PTX 304.

11:22:04 12 Dr. Kuhn, referring back to your timeline, let's
11:22:07 13 talk about the next entry which is FDA Rule 21 CFR 201.323.
11:22:16 14 Let's turn to PTX 243 in your binder.

11:22:25 15 A. Yes, I found it. Thank you.

11:22:26 16 Q. Is this a 2000 FDA rule titled Aluminum in Large and
11:22:31 17 Small Volume Parenteral used in Total Parenteral Nutrition
11:22:35 18 that you considered in the course of forming your opinions
11:22:37 19 in this case?

11:22:37 20 A. Yes, it is.

11:22:38 21 Q. Mr. Doyle, I would like to pull up PDX 314, please.

11:22:42 22 So Dr. Kuhn, I'm showing you PDX 314 which is an
11:22:44 23 excerpt of page 1 of the FDA rule. Would you please explain
11:22:51 24 to us, what is a small volume parenteral?

11:22:54 25 A. A small volume parenteral are typically parenteral

11:22:59 1 solutions at a hundred mLs volume or smaller that we use in
11:23:04 2 IV solutions, IV graphs, et cetera.

11:23:08 3 Q. And are cysteine products for TPN considered small
11:23:12 4 volume parenteral?

11:23:13 5 A. Yes, they are.

11:23:14 6 Q. So this rule came in 2000, so finally fifteen years
11:23:18 7 after Sedman the FDA is taking action on this issue?

11:23:21 8 A. Yes.

11:23:23 9 Q. Okay. Dr. Kuhn, I'm showing you PDX 315 which is two
11:23:29 10 excerpts of pages 2 and 3 of the FDA rule. What
11:23:34 11 requirements did the 2000 FDA rule impose on small volume
11:23:39 12 parenteral?

11:23:39 13 A. For the first time I'm aware of practicing
11:23:42 14 pharmacists, it now said that the maximum level of aluminum
11:23:46 15 at expiration or the end of the shelf life had to be stated
11:23:51 16 on the actual container that we might use in preparation.
11:23:54 17 Okay? So that pharmacist or technician could look at that
11:23:57 18 and say let's label relative to the ingredient, in this
11:24:02 19 case, aluminum, and it should come under the phrase contains
11:24:05 20 no more than X amount of micrograms per liter of aluminum.
11:24:10 21 And that --

11:24:11 22 THE COURT: I'm sorry, what year did you say
11:24:13 23 that was?

11:24:14 24 THE WITNESS: 2000. I'm sorry, Your Honor.

11:24:16 25 So this was the proposed new final rule in 2000

11:24:22 1 that that was stated on the label. And that there were
11:24:27 2 limits proposed at large volume parenteral as well, so it
11:24:32 3 talked not only about small volume parenteral which would
11:24:35 4 include cysteine, but large volume, the dextrose and those
11:24:40 5 things.

11:24:40 6 Q. Did the 2000 FDA rule also include warning language?

11:24:44 7 A. Yes. So it also had to say this product contains
11:24:48 8 aluminum that can be toxic. And it suggests and notes that
11:24:53 9 to remind people that these levels of 4 to 5 micrograms per
11:24:58 10 kilo per day is when we can see accumulation of aluminum
11:25:04 11 which can be associated with both the neuro toxins we talked
11:25:09 12 about and the bone toxins, so it's warning people to say
11:25:14 13 okay, remember that you're using these products, they
11:25:19 14 contain aluminum and you need to think about it, in my
11:25:24 15 opinion.

11:25:29 16 Q. Dr. Kuhn, I'm showing you PDX 316 which is an excerpt
11:25:34 17 of page 4 of the FDA rule. What did you understand to be
11:25:39 18 the purpose of the required statement of maximum aluminum
11:25:44 19 concentration in small volume parenteral at the time of
11:25:49 20 expiry?

11:25:54 21 A. Well, as a pharmacist and helping prepare this, it
11:25:59 22 would be really nice to know how much aluminum might be in
11:26:04 23 the products I'm using. So this maximum concentration
11:26:09 24 allows someone like me to say how much aluminum would this
11:26:14 25 product have and this product would have. We know what the

11:25:55 1 upper limit is, but that's all we're given. And then that
11:26:00 2 will allow us to at least start to attempt and calculate how
11:26:05 3 much exposure the child might have.

11:26:06 4 Q. Is there a reason why you would use the maximum
11:26:09 5 concentration aluminum expiry in your calculation?

11:26:13 6 A. Because we don't assay for life these small volume
11:26:20 7 parenterals and it's the only number we have. I can't make
11:26:23 8 a number up. I don't mean to be flip about that. If we're
11:26:26 9 going to make a calculation, you have to give me some
11:26:29 10 numbers to work with. And if I was trying to minimize
11:26:32 11 aluminum, then give me the upper range so at least I look at
11:26:35 12 that, if it's a little bit less, that's better, but I have
11:26:38 13 to have some numbers to start with.

11:26:41 14 Q. And when was this FDA rule implemented?

11:26:43 15 A. If I remember, it was July 2004, there were some
11:26:46 16 comments made and some additional time went on, I guess
11:26:50 17 three-and-a-half years later.

11:26:53 18 Q. What impact did the FDA regulation have on your
11:26:56 19 practice as a pediatric clinical pharmacist?

11:27:02 20 A. Now that we had the label maximum of aluminum, we can
11:27:05 21 now start to calculate how much aluminum exposure our
11:27:08 22 individual babies were getting and start looking at trends,
11:27:11 23 at least now we could do the calculation. We were
11:27:14 24 encouraged to try to limit.

11:27:17 25 Q. At the time the rule was implemented, were you able

11:27:24 1 to meet that aluminum exposure target?

11:27:27 2 A. Given these ranges, or given these numbers we were
11:27:30 3 unable to do that.

11:27:31 4 Q. Why not?

11:27:33 5 A. The math didn't work. When you start with very -- it
11:27:37 6 says greater -- or no less than 5,000 or no less than 2,000
11:27:41 7 and you add all the ingredients together, you get a number
11:27:45 8 that's extremely above 4 to 5 mics per kilo.

11:27:49 9 Q. Mr. Doyle, I would like to pull up PDX 304, please.

11:27:51 10 Dr. Kuhn, let's take a look at the next entry in
11:27:51 11 your timeline which is the 2005 Driscoll paper. If you
11:28:01 12 would, please, turn to PDX 189 in your binder.

11:28:01 13 A. Yes, I found it.

11:28:10 14 Q. Is this a 2005 article by Driscoll titled Calculating
11:28:11 15 Aluminum Content in Total Parenteral Nutrition in Mixtures
11:28:11 16 that you considered in forming your opinions in this case?

11:28:21 17 A. Yes, I did.

11:28:21 18 Q. Mr. Doyle, I would like to pull up PDX 317.

11:28:21 19 Dr. Kuhn, I'm showing you PDX 317 which is an
11:28:31 20 excerpt of page 1 of the Driscoll article. What do the
11:28:31 21 articles of Driscoll do as part of this commentary?

11:28:31 22 A. Now that the rule had been finalized by the FDA in
11:28:41 23 2004, Dr. Driscoll and -- the two Dr. Driscoll's put
11:28:41 24 together and actually calculated based on labeled maximum
11:28:51 25 aluminum a number of simulated TPNs that pharmacists could

11:28:56 1 look at and say well, this is depending on the amount of
11:28:59 2 dextrose, amino acids, and you add calcium, what are the
11:29:04 3 amounts of aluminum that you could actually calculate. And
11:29:07 4 they also stated based on the FDA's ruling, and I think as a
11:29:12 5 professional pharmacist that it's our responsibility to do
11:29:15 6 that calculation as best we can to help calculate the daily
11:29:19 7 aluminum exposure as we are working with our babies.

11:29:23 8 Q. Dr. Kuhn, I'm showing you PDX 318, which is an
11:29:28 9 excerpt of page 1 of Driscoll. Did the Driscoll article
11:29:31 10 identify any specific component that contributed to the
11:29:34 11 aluminum content in these TPN solutions?

11:29:37 12 A. They actually look at a fairly exhaustive list of all
11:29:41 13 the common nutrients we use to prepare a TPN and identified
11:29:44 14 the three big offenders, the phosphate salts, cysteine
11:29:53 15 hydrochloride and calcium.

11:29:56 16 Q. So the cysteine was one of the big three offenders?

11:30:01 17 A. Yes, it was.

11:30:02 18 Q. What was the aluminum content of the cysteine
11:30:02 19 hydrochloride component according to their calculations?

11:30:07 20 A. Labeled as no more than 15,000 micrograms per liter.

11:30:12 21 Q. Dr. Kuhn, I'm showing you PDX 319 which is an excerpt
11:30:12 22 of pages 3 and 4 of Driscoll.

11:30:20 23 A. Yes. Doing the calculation and looking at their
11:30:25 24 simulations, there was really no way with the number of
11:30:28 25 calculations they did and the formulas that -- that you

11:30:32 1 could come even close to five micrograms per kilo per day.
11:30:36 2 It wouldn't be possible.

11:30:37 3 Q. Is that consistent with your experience compounding
11:30:40 4 TPN solutions at that time?

11:30:42 5 A. Yes, of course.

11:30:42 6 Q. And Mr. Doyle, I would like to pull up PDX 304,
11:30:47 7 please. Let's move on to the next entry in your timeline
11:30:51 8 which is the Poole article. If you would, please, turn to
11:30:55 9 PTX 156 in your binder.

11:31:02 10 A. Yes, I'm there.

11:31:03 11 Q. Is this a 2008 article by Poole titled Aluminum
11:31:08 12 Exposure from Pediatric Parenteral Nutrition: Meeting the
11:31:12 13 New FDA Regulation that you considered in the course of
11:31:14 14 forming your opinions in this case?

11:31:16 15 A. Yes, it is.

11:31:17 16 Q. If I could, Mr. Doyle, please pull up PDX 320.

11:31:21 17 Dr. Kuhn, are you familiar with Dr. Robert
11:31:24 18 Poole?

11:31:24 19 A. Yes, Dr. Poole is a director of pharmacy at Stanford
11:31:30 20 Children's Hospital. I believe it's the Lucile Packard
11:31:32 21 Children's Hospital. And we were on the board of the
11:31:32 22 National Pediatric Pharmacy together and also colleagues for
11:31:40 23 about twenty years. And I had a number of conversations
11:31:42 24 about TPN and aluminum and a few other things.

11:31:42 25 Q. Dr. Kuhn, I'm showing you PDX 321 which is an excerpt

of page 2 of Poole. What did the authors of the Poole article do as part of their study?

A. They actually looked at about over a hundred marketed products that we might use in TPN and used the software that they were using for samples of actual TPNs they made in 2004 and in 2006, and calculated based on those labels what the amount of aluminum exposure would be for those children and then stratified them by weight.

Q. And Dr. Kuhn, I'm showing you PDX 322 which is an excerpt of page 3 of Poole. What did the calculation show?

A. What you can see in the highlighted sections between 2006 and 2004, so two separate years, they looked at quite a number of different TPNs and found that they all exceeded the 4 to 5 micrograms per kilo, except for children who weighed more than 50 kilos or 110 pounds. Sometimes we do have some adolescents who do get TPN, but if you look particularly at those children who weigh less than 50 kilos, you see the numbers of 27, 30, 59, 50, they're very much elevated over what the target goal would be.

Q. Dr. Kuhn, I'm showing you PDX 323 which is an excerpt of page 4 of the Poole article. What did the Poole authors conclude from their study?

A. Like the Driscoll calculations, they also showed that there was no way to meet the July 2004 FDA rule of less than five mics per kilo per day of exposure to TPN.

Kuhn - direct

11:33:35 1 Q. Was this consistent with your own experience?

11:33:38 2 A. Yes, unfortunately.

11:33:39 3 Q. Mr. Doyle, will you please pull up PDX 304. Thank
11:33:45 4 you.

11:33:45 5 Referring back to your timeline, let's go to the
11:33:49 6 next entry which is Hernandez-Sanchez. If could go to PDX
11:33:56 7 152 in your binder.

11:34:02 8 A. Yes, I found it.

11:34:03 9 Q. And is this a 2013 article by Hernandez-Sanchez
11:34:07 10 entitled Aluminum and Parenteral Nutrition, a Systematic
11:34:11 11 Review that you considered in the course of forming your
11:34:14 12 opinions in this case?

11:34:14 13 A. Yes.

11:34:15 14 Q. Mr. Doyle, I would like PDX 324, please.

11:34:19 15 Dr. Kuhn, I'm showing you PDX 324 which is an
11:34:23 16 excerpt of page 1 of Hernandez-Sanchez and I would like to
11:34:27 17 direct you to the very first sentence of the article. Do
11:34:29 18 you agree with Hernandez-Sanchez that as of 2013 the
11:34:33 19 aluminum toxicity problem in parenteral nutrition solutions,
11:34:36 20 TPNs, is decades old and still unresolved?

11:34:40 21 A. Clearly.

11:34:41 22 Q. So it had been twenty-seven years since the seminal
11:34:44 23 Sedman article, correct?

11:34:47 24 A. Yes.

11:34:50 25 Q. Dr. Kuhn, I'm showing you PDX 325 is an excerpt of

11:34:57 1 page 2 of Hernandez-Sanchez. What components did
11:35:01 2 Hernandez-Sanchez identify as the largest contributors of
11:35:07 3 aluminum to parenteral nutrition solutions?

11:35:07 4 A. So consistent with observations of others, it was
11:35:10 5 calcium gluconate, inorganic phosphates any cysteine
11:35:15 6 hydrochloride.

11:35:16 7 Q. So we recognize cysteine hydrochloride is one of the
11:35:20 8 big offenders?

11:35:21 9 A. That's right.

11:35:21 10 Q. Dr. Kuhn, I'm showing you PDX 326 which is page 7.
11:35:27 11 What does Hernandez-Sanchez conclude with regarding the
11:35:31 12 ability to meet the FDA guidelines on minimum aluminum
11:35:34 13 exposure?

11:35:35 14 A. Consistent with some of the other articles we talked
11:35:38 15 about, they were unable to meet the FDA guidelines of less
11:35:42 16 than five, and that this is a continuing problem, and we
11:35:47 17 need to continue -- it's an ongoing problem, that they
11:35:53 18 really saw the same kind of observations that previous
11:35:56 19 people had done.

11:35:58 20 Q. So now we're nine years after the FDA regulation took
11:36:03 21 effect in 2004 and still it was virtually impossible to meet
11:36:07 22 that regulation?

11:36:08 23 A. That is correct.

11:36:11 24 Q. Dr. Kuhn, I'm showing you PDX 327 which is an excerpt
11:36:15 25 of page 8 of Hernandez-Sanchez.

11:36:19 1 Did Hernandez-Sanchez provide any recommendation
11:36:22 2 for reducing aluminum in TPN solutions?

11:36:25 3 A. Yes, they did.

11:36:26 4 Q. What were those recommendations?

11:36:28 5 A. Manufacturers should improve manufacturing
11:36:30 6 techniques. Obviously if we could get product that had
11:36:33 7 lower aluminum, that would be a great start. Okay? And
11:36:36 8 that all health care providers should do their best to try
11:36:39 9 to minimize exposure of aluminum in parenteral nutrition,
11:36:45 10 and that my choosing, hopefully choosing products with the
11:36:51 11 least amount of aluminum we're going to decrease the overall
11:36:55 12 exposure to these.

11:36:56 13 Q. Does Hernandez-Sanchez recommend how manufacturers
11:36:56 14 should improve their manufacturing technique to provide low
11:37:03 15 aluminum products?

11:37:03 16 A. No, they did not.

11:37:04 17 Q. Were Hernandez-Sanchez's recommendation to health
11:37:07 18 care providers consistent with the practice in your
11:37:09 19 pharmacy?

11:37:10 20 A. Yes, they were.

11:37:12 21 Q. Mr. Doyle, if I could go to PDX 304, please. Let's
11:37:17 22 go back to the timeline and take a look at the last entry
11:37:20 23 which is Lima-Rogel. Turn to PDX 153 in your binder.

11:37:32 24 A. Yes.

11:37:32 25 Q. Is this a 2016 article by Lima-Rogel titled Aluminum

11:37:39 1 Contaminants in Parenteral Nutritional Mixtures for Low
11:37:43 2 Pre-birth Weight in Mexico that you considered in forming
11:37:47 3 the opinions in this case?

11:37:49 4 A. Yes, it is.

11:37:50 5 Q. Mr. Doyle, can we go to PDX 328. Dr. Kuhn, I'm
11:37:55 6 showing PDX 328 which is an excerpt from page 1 of
11:38:00 7 Lima-Rogel. I would like to direct you to the very first
11:38:03 8 sentence in the Lima-Rogel article. Do you agree that even
11:38:06 9 as late as 2016 aluminum contamination from intravenous
11:38:12 10 solutions still represents an unsolved chemical and
11:38:15 11 biochemical problem?

11:38:15 12 A. Yes.

11:38:15 13 Q. Was this consistent with your own experience making
11:38:20 14 TPN solutions for neonatal patients?

11:38:23 15 A. Yes.

11:38:23 16 Q. Now, Dr. Kuhn, you personally have compounded TPN
11:38:27 17 solutions for many years, right?

11:38:29 18 A. That is correct.

11:38:29 19 Q. And approximately how long have been compounding TPN
11:38:33 20 solutions?

11:38:33 21 A. I actually started as a pharmacy intern in 1979,
11:38:37 22 primarily making adult ones in the first hospital I worked
11:38:42 23 at. But I have been making them pretty much ever since.

11:38:45 24 Q. That's over forty years?

11:38:45 25 A. Unfortunately. I mean yes.

Kuhn - direct

11:38:48 1 Q. And did you ever use the Sandoz cysteine product in
11:38:52 2 any of these TPN solutions?

11:38:54 3 A. Yes, we did.

11:38:55 4 Q. So you're familiar with the Sandoz product and its
11:38:59 5 labeling?

11:38:59 6 A. Yes.

11:39:01 7 Q. Dr. Kuhn, I'm showing you PDX 329 which is excerpts
11:39:08 8 of pages 2 and 5 of the Sandoz label. So is this the label
11:39:13 9 for the Sandoz product?

11:39:14 10 A. Yes, I believe it is, yes.

11:39:14 11 Q. And was the Sandoz product FDA approved?

11:39:14 12 A. Not to my knowledge.

11:39:20 13 Q. What was the aluminum level in the Sandoz product?

11:39:23 14 A. Well, as labeled it says it contains no more than
11:39:27 15 5,000 micrograms per liter of aluminum.

11:39:30 16 Q. What does that mean?

11:39:31 17 A. That means it has something less than 5,000
11:39:34 18 micrograms per liter. I don't know how much, but less than
11:39:38 19 5,000.

11:39:38 20 Q. And in your opinion, was that an acceptable amount of
11:39:42 21 aluminum?

11:39:42 22 A. No, it wasn't.

11:39:42 23 Q. Why not?

11:39:42 24 A. Well, since the only standard that we had was what's
11:39:42 25 labeled, the standard was to take that maximum amount and

11:39:53 1 actually do a calculation to see how much exposure a
11:39:57 2 particular patient would get.

11:39:58 3 Q. Have you prepared a slide explaining this
11:40:01 4 calculation?

11:40:01 5 A. Yes.

11:40:02 6 Q. And Dr. Kuhn, I'm showing you PDX 330. Is this your
11:40:06 7 calculation?

11:40:06 8 A. Yes.

11:40:07 9 Q. And would you please explain how you did this
11:40:09 10 calculation?

11:40:10 11 A. Well, the amount of cysteine we add is dependent on
11:40:13 12 the overall grams of amino acid. Typically we had
11:40:16 13 40 milligrams of cysteine per gram of amino acid that would
11:40:20 14 mean that based on the 50 milligrams of cysteine per mL,
11:40:23 15 each kilogram, each kilogram the baby weighs is .8 mL, and
11:40:27 16 because we use three-and-a-half grams per kilo of amino
11:40:30 17 acid, that works out it's actually 2.8 mLs of cysteine per
11:40:34 18 kilo per day for every child. When you do the calculation
11:40:37 19 based on the labeled amount of aluminum, that would work out
11:40:41 20 to 14 micrograms of aluminum per kilo per day.

11:40:44 21 Q. How does that compare to the FDA limit for daily
11:40:48 22 exposure of aluminum?

11:41:01 23 A. It's more than twice the limit.

11:41:04 24 Q. And why do you use the labeled amount of aluminum to
11:41:08 25 calculate the daily aluminum exposure?

11:41:08 1 A. That's the only number I have to calculate.

11:41:12 2 Q. Is there any risk involved in using a smaller number?

11:41:17 3 A. Well, I think there would be risk to know, if you

11:41:21 4 knew what it was, but you have to assume it's at the labeled

11:41:26 5 amount when you're doing your calculation and it may be less

11:41:30 6 than that, but I don't know that. As a pharmacist, I have

11:41:32 7 no way to know that.

11:41:34 8 Q. Do the --

11:41:35 9 A. Any pharmacist. Pardon me.

11:41:38 10 THE COURT: Is the label less than or equal to

11:41:41 11 or just less than?

11:41:42 12 THE WITNESS: Less than, Your Honor.

11:41:43 13 THE COURT: So why did you use 5,000 if it's

11:41:44 14 less than 5,000.

11:41:47 15 THE WITNESS: I guess I could have used 4,999,

11:41:51 16 but typically --

11:41:52 17 THE COURT: The point is the same.

11:41:54 18 THE WITNESS: Yes. Yes, Your Honor.

11:41:58 19 Q. Did the TPN solutions you compounded using the Sandoz

11:42:02 20 products exceed FDA daily maximum exposure limit?

11:42:05 21 A. Yes.

11:42:06 22 Q. If the Sandoz product had an unacceptable level of

11:42:10 23 aluminum, why did you use it?

11:42:12 24 A. Well, as we mentioned before, neonates have no

11:42:15 25 caloric reserve, so weighing the amount of calcium and

phosphorus that they need and the fact that they need cysteine for those oxidative stress and all the protein synthesis, you weigh that against the potential risk of aluminum. So to deprive those children the calcium phosphorus they need, to prevent them from getting cysteine which we know most need, that outweighs the potential toxicity of aluminum. It's not an ideal situation, but it's the only situation we could use.

Q. And what would be the harm of not administering cysteine to a neonatal?

A. As I mentioned before, you could not give them additional calcium and phosphorus. You probably have poor protein synthesis which would lead to poor growth. Remember in these children we're trying to simulate what mom does in the last trimester which is to quadruple their weight in the last three months, that's why women's physiology and anatomy changes a lot in the last trimester. For those reasons and the fact that they have no caloric reserve, we have no option but to give it to them. And that's been I think the approach of neonatologists and clinicians across the country is to go ahead and give cysteine whenever we can in this population.

Q. If you didn't include cysteine, would you also lose a stabilizing benefit that you mentioned previously?

A. As a pharmacist, yes, I would lose that increased

Kuhn - direct

11:44:05 1 calcium phosphorous, when you diluted it that's the reason
11:44:09 2 why I couldn't give more calcium phosphorous because now the
11:44:14 3 solubility has changed and I can't give as much calcium
11:44:17 4 phosphorous and we're talking three or four or five ounces
11:44:21 5 total fluid for 24 hours.

11:44:24 6 Q. Mr. Doyle, I would like to pull up PDX 304.

11:44:28 7 Mr. Kuhn, looking back to your timeline which
11:44:30 8 runs from 1985 to the present, to your knowledge over what
11:44:33 9 period of time was the Sandoz product available?

11:44:36 10 A. As I remember, it was the mid 2000s, so 2005, 2007,
11:44:45 11 somewhere in the mid 2000s was my recollection.

11:44:49 12 Q. Up through when?

11:44:51 13 A. I guess 2017, 2019.

11:44:56 14 Q. So in your opinion, was there a long-felt, unmet need
11:45:00 15 for a low aluminum cysteine component of TPN solutions even
11:45:05 16 though the Sandoz product was available at that time?

11:45:07 17 A. Yes.

11:45:10 18 Q. And Dr. Kuhn, does that long-felt but unmet need for
11:45:14 19 a low aluminum cysteine product for TPN solutions still
11:45:19 20 exist?

11:45:21 21 A. No, it doesn't, not today.

11:45:21 22 Q. Why not?

11:45:22 23 A. Well, with now a lower cysteine product that we have
11:45:26 24 a much lower aluminum and reduction of calcium salt and even
11:45:31 25 some reduction in phosphates we're able to get our numbers

11:45:35 1 down into that range of 3 to 4 micrograms per kilo routinely
11:45:40 2 so we really have come a long way to try and address this
11:45:43 3 issue.

11:45:43 4 Q. You mentioned a low aluminum cysteine product. Which
11:45:47 5 product is that?

11:45:47 6 A. The ELCYS.

11:45:50 7 Q. Do you currently use ELCYS in your TPN solutions
11:45:54 8 compounded in your pharmacy?

11:45:55 9 A. Every day, including today.

11:45:56 10 Q. When did you first start using ELCYS?

11:46:00 11 A. Well, I believe it was made available in late spring
11:46:04 12 early summer of 2019. Once we found out about it and looked
11:46:08 13 at it closely, we made the switch pretty quickly.

11:46:12 14 Q. And what was the reaction in your field to the
11:46:14 15 introduction of ELCYS?

11:46:15 16 A. I think for those people who were made aware that
11:46:18 17 this was a product available, the uptake was pretty fast.
11:46:23 18 But I think sometimes people were unaware that this product
11:46:26 19 was available, and so I think getting the word out so to
11:46:30 20 speak was important. But over time it certainly -- over
11:46:32 21 time it became the standard to use.

11:46:32 22 Q. Did the introduction of ELCYS affect the way your
11:46:42 23 hospital used cysteine and TPN solutions?

11:46:45 24 A. Our solution because as I mentioned before, not only
11:46:48 25 do infants require cysteine, but probably older pediatric

11:46:54 1 patients to some degree might need them as well and it's
11:46:58 2 documented, but we can also use cysteine in older pediatric
11:47:02 3 patients, one and two-year olds to increase their calcium
11:47:06 4 and phosphorus solubility, so we use it not only to give
11:47:11 5 them cysteine that they might need, you also increase the
11:47:15 6 solubility of calcium phosphorous, so we routinely, in
11:47:21 7 children under two we routinely add cysteine. Two years of
11:47:26 8 age, pardon me, not two months.

11:47:27 9 Q. What did you do when you were first considering using
11:47:30 10 ELCYS?

11:47:31 11 A. Well, we looked at the labeling. Okay? Looked at
11:47:34 12 availability like we would with any product. And then we
11:47:37 13 evaluated it based on what we could compare it to the
11:47:41 14 standard we were using.

11:47:44 15 Q. So Mr. Doyle, could I please get PDX 331.

11:47:50 16 Dr. Kuhn, I'm showing you PDX 331 which is an
11:47:54 17 excerpt of JTX 13M at page 11698. Dr. Kuhn, is this the
11:48:00 18 ELCYS label that you reviewed?

11:48:04 19 A. Yes.

11:48:05 20 Q. What are some of the key pieces of information
11:48:08 21 included in the ELCYS label?

11:48:09 22 A. Well, almost any parenteral you have indications for
11:48:13 23 use, dosage, administration, precautions, method of
11:48:16 24 administration and instructions, so all the things one would
11:48:20 25 need to know about the product, how do administer it and

11:48:26 1 prepare it prior to dispensing it for a child.

11:48:29 2 Q. Dr. Kuhn, I'm showing you PDX 332 which is an excerpt
11:48:35 3 of the ELCYS label. Is this the preparation and mixing
11:48:40 4 instructions that you were referencing?

11:48:41 5 A. Yes.

11:48:42 6 Q. And Dr. Kuhn, I'm showing you PDX 333 which is an
11:48:46 7 excerpt of the ELCYS label at page 117000. What are you
11:48:52 8 showing on this slide?

11:48:53 9 A. This is actually the recommended dosage for pediatric
11:48:57 10 patients and adults. As you can see that we talked about
11:49:00 11 before, the first column talks about how much amino acids a
11:49:04 12 particular child would need based on age, the recommended
11:49:08 13 dosage of ELCYS, and then the volume, that is graduated down
11:49:13 14 to adults. There are some adults who are very critically
11:49:18 15 ill and who have liver disease that probably need cysteine
11:49:23 16 as well, so it gives you a chart of suggested and
11:49:28 17 recommended dosage.

11:49:27 18 Q. Does the ELCYS label provide instructions for
11:49:31 19 treating a patient with ELCYS?

11:49:31 20 A. Yes.

11:49:32 21 Q. Are the instructions provided in the ELCYS label
11:49:35 22 consistent with how you use ELCYS in your pharmacy?

11:49:38 23 A. Yes.

11:49:39 24 Q. Dr. Kuhn, I'm showing you PDX 334 which is an excerpt
11:49:42 25 of the ELCYS package at page 11704. Does the ELCYS label

17:48:55 1 more than two percent total, so it's got to be -- if it's in
17:48:58 2 there at all, it's got to be less than, but in any event,
17:49:01 3 you say at least that you have some evidence that certain
17:49:05 4 peaks more likely than not are pyruvic acid and those peaks
17:49:10 5 are certainly in there at less than two percent.

17:49:13 6 DR. WHITLEY: Yes, Your Honor.

17:49:14 7 THE COURT: Okay. So what would help me is if
17:49:18 8 anyone can find, if you can, some case law about like what
17:49:24 9 less than means, and does it mean that you have to have
17:49:28 10 some.

17:49:29 11 MR. BENCHELL: Yes, Your Honor.

17:49:29 12 THE COURT: All right. So thank you. That was
17:49:33 13 interesting. And we'll see you tomorrow at 8:30.

17:49:45 14 Wait, I was told to ask if Dr. Aloha's
17:49:49 15 deposition is being read tomorrow because we have a dispute.

17:49:52 16 MS. DRAKULICH: Yes, I believe it is now, in
17:49:54 17 light of the expedited schedule it will be read tomorrow.

17:49:58 18 THE COURT: All right. Thank you.

19 (Court adjourned at 5:49 p.m.)
20

21 I hereby certify the foregoing is a true and
22 accurate transcript from my stenographic notes in the proceeding.

23 /s/ Dale C. Hawkins
24 Official Court Reporter
25 U.S. District Court

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