Dr. Brian Lee—Autism & maternal medication use

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Sara Whitlock, SciLine [00:00:12] Hi, everyone. Thanks for joining today's media availability with Dr. Brian Lee about autism and maternal medication use. This media format is pretty new for SciLine, so please bear with us if anything strange happens on the technological side. I'm Sara Whitlock, and I work for SciLine. Because this is a webinar, Zoom does not allow us to give reporters permission to record directly. If you use a third-party software to record videos, you have our permission to do so, and everyone will receive our recording of the video as soon as we can get it out, usually within 30 minutes of when we wrap. You'll also receive a second email with a transcript a little bit after that. I have a few questions that I'm going to ask Brian, whose biography I won't recite. It's on the website where you all signed up for this. So I'm gonna ask Brian a few question to kick things off. And then we will open it up for reporter questions. And you can ask your questions by using the raise your hand feature in Zoom. So Brian, first things first. Please say and then spell your name and then give us your title.

Dr. Brian Lee [00:01:08] Sure. My name is Brian Lee. That's B-R-I-A-N-L-E-E. I am a professor of epidemiology and biostatistics at Drexel University.

Sara Whitlock, SciLine [00:01:20] Thanks so much. So you study how prenatal medication use affects children's neurodevelopmental outcomes. What can you tell us about any link between autism and the use of acetaminophen, which is the active ingredient in Tylenol during pregnancy?

Dr. Brian Lee [00:01:34] So our study published last year in JAMA looked at 2.5 million pregnancies and followed the moms and the children for up to 20 years in Sweden. And what we found was a two-part story. So at first, when we looked at the kids of users, acetaminophen users versus non-users, we found a slight statistical increase in risk of autism and ADHD. But association is not causation, and we wanted to look at this further. When we look at users versus non-users, this is kind of an apples to oranges comparison because the users are so different in many ways. People who take acetaminophen are different because they are sicker. They have a medical condition that needs treatment. So right away, that's one thing that differentiates between users and non-users. So infections during pregnancy, fevers, pregnancy pain. And then another thing, the big elephant in the room for neurodevelopmental disorders is genetics. Autism is a highly heritable condition. And genetics, when you just look at users versus non-users, it sort of ignores that aspect. So the second part of our story was that we wanted to look at whether or not familial factors like genetics could potentially explain the statistical association. And so we looked at siblings born to the same mother. So, but one sibling was exposed and the other sibling was unexposed. And when we did it this way, the apparent risk completely flatlined and disappeared. In other words, there was no increase in risk of autism or ADHD associated with acetaminophen use. And what that told us was that familial confounding factors such as maternal genetics were likely explaining the apparent statistical association.

Sara Whitlock, SciLine [00:03:41] Gotcha, thanks so much. So if we change gears slightly, is there any known link between a mother receiving vaccines during pregnancy and a child going on to develop autism?

Dr. Brian Lee, Drexel [00:03:52] The numerous studies to date on that topic have shown over and over again that there does not appear to be a credible evidence base to support that association.

Sara Whitlock, SciLine [00:04:04] Thanks so much. And we also heard today about folic acid and leucovorin, a drug that is derived from folic acid. Can you tell us a little bit about what is known and what is being studied about folic acid and autism?

Dr. Brian Lee, Drexel [00:04:17] So first of all, folic acid is an incredibly important nutrient that we know affects neurodevelopment. It's been 30 years plus since folic acid deficiencies were linked with neural tube defects, so the idea that folic acid is somehow important for neurodevelopment, no one is questioning that. The difficulty with promoting leucovorin at this time is that the existing evidence for leucovorin and for treatment or alleviation of autism symptoms is remarkably premature. There's only been a handful of very small studies which have some methodological issues, but no therapeutic recommendations, in my opinion, should be made based on this really preliminary evidence. In short, more research is needed.

Sara Whitlock, SciLine [00:05:13] That makes a lot of sense. And is it true that rates of autism diagnosis are increasing? And if so, how much are they increasing? And can you briefly describe some of the reasons why scientists think that this is happening?

Dr. Brian Lee, Drexel [00:05:25] Sure. So it's not under debate. Rates of autism diagnoses are increasing. A large part of this is of course going to be due to increasing awareness, changing diagnostic criteria, and just better recognition of autism symptoms in schools. And so I think the part that's up for debate is whether or not environmental factors are contributing to this increase. And certainly I don't think most scientists are ruling that aspect out, but I think as far as, you know, pointing the finger at acetaminophen, I don't think that's a credible suspect.

Sara Whitlock, SciLine [00:06:11] Makes a lot of sense. If a mother gets a fever during pregnancy, we do know that that poses risks to the fetus. What does the research say about which is worse for the fetus? A mother having untreated fever during the pregnancy, or one who's using Tylenol to treat their fever?

Dr. Brian Lee, Drexel [00:06:27] Thanks, that's a really great question. And this is the part where my limitations come in. I'm not a clinician so I can't speak for this, but this is one of those areas where talk to your doctor about this if you are concerned. But fevers are a known quantity as far as potential adverse effects. And certainly the evidence base for fevers being harmful is a lot stronger in my opinion, than for acetaminophen being harmful. At least at recommended doses.

Sara Whitlock, SciLine [00:07:02] Thank you so much. And yeah, we'd urge reporters to always be in contact with their local physicians. So now we're going to turn to questions from our audience. So if any reporters on the line have questions, please use the raise your hand function in Zoom and we will call on you in the order that you raise your hand. When we call on, we ask that you say your name and your outlet before you ask your question. And just as a reminder to everyone who's on the line, Dr. Lee is a scientist who studies how maternal medication used during pregnancy affects child neurodevelopmental outcomes. So keeping your questions focused on that part of the science will be best suited to his expertise. All right, so we have our first question from Karen Wright. Karen, if you can say your name, outlet, and question, please.

Karen Wright, KMSU Minnesota [00:07:44] My name is Karen Wright. I'm with KMSU Radio. It's an independent public radio in Minnesota. And my question is, have there been

studies and research on mothers who use mental health medications during pregnancy related to autism, whether it's, I guess, any kind of mental health? Because a lot of them are classified as more harmful in some cases. And a clinician will give it to the... the mother if it's more warranted that she would harm herself versus the harm of the baby.

Dr. Brian Lee, Drexel [00:08:21] That's an excellent question. So there has been indeed a number of studies looking at mental health medications during pregnancy and child autism. Our team has done several in fact, but the majority of studies and the consensus seems to point towards no increase in risk associated with antidepressants, for example, which is probably the most studied mental health medication. Other studies have looked at antipsychotic use and have also concluded that there's no apparent increase in risk. One additional note is that the maternal mental health condition has been genetically associated with other mental disorders, including autism. So this is one of those things that studies try to tease apart. Is it the medication that is linked with autism or is it actually the mental health condition being treated? And that's a very difficult thing to tease apart, but the majority of studies suggest that it's not the mental health medication, that there's no apparent increase in risk associated with that.

Sara Whitlock, SciLine [00:09:45] Great, thank you so much. Our next question is from Shelley Schlender, and if you can go ahead and say your name, outlet, and your question, please.

Shelley Schlender , KGNU Boulder [00:09:53] All right, can you hear me okay? Sounds great. Loud and clear. I'm Shelley Schlender. I'm with KGNU Boulder, Denver in Colorado. There's a recent Cedar Sinai study about Tylenol and ADHD and autism that contradicts your study. In that study research paper, it did indicate some reasons why there were thoughts that Tylenols drugs could cross the placenta and increase, I think it was inflammation. It's a very different result than your study. Can you comment on that?

Dr. Brian Lee, Drexel [00:10:29] Certainly. So the paper you're referencing is by Prada et al. And it came out in the last month or two. And what that study was, was a review, a quality-weighted review of the existing evidence. In other words, it's not a new study, but rather it's a new look at old studies. And the studies, they've up-weighted, they more... Emphasize the studies that they believe to be high quality, and they sort of disregard the studies they believe be lower quality. And this is where scientists will disagree on what one person perceives to be a high quality and another person might not believe or agree with. And so the conclusions that they reach in this paper are not necessarily what other scientists would agree on. Um, now as far as the animal evidence goes, that's actually quite mixed as well. And I'm not an animal expert, but my reading of the literature suggests that this is not at all a unanimous sort of a, oh, if you give acetaminophen to a pregnant rat, you're going to cause rat autism or anything of that sort. The study, in my opinion, is a fairly selective cherry-picked analysis of the evidence to date.

Sara Whitlock, SciLine [00:12:06] That makes sense. Thank you. And our next question is from Amy Nay. So Amy, if you could say your name, outlet, and question, please.

Amy Nay, Fox 13 Salt Lake City [00:12:16] All right, hi there, it's Amy Nae. Can you hear me? All right. Amy Naeh here from Fox 13 News in Salt Lake City. Thanks so much. We appreciate your time and your expertise on this matter. A question regarding this announcement. Does this change current recommendations at all for pregnant women? I spoke to a local pharmacist and he said it's still early in these stages for this link and more

needs to be done before he would go as far as changing that. Is that something that you would agree with?

Dr. Brian Lee, Drexel [00:12:46] I believe current recommendations at this point are lowest dose possible for the shortest time possible. And I don't think anything changes with any pronouncement by the government. If you ask the expert clinician bodies like the Society for Maternal Fetal Medicine and the American College of Obstetrics and Gynecology or any number of other expert sort of bodies, they've all reached the conclusion that there's no strong evidence to support that acetaminophen use during pregnancy increases risk of autism or ADHD.

Sara Whitlock, SciLine [00:13:29] Sounds great. Our next question is from Chris O'Connell. Chris, if you can say your name, outlet, and question.

Chris O'Connell, Fox 29 Philadelphia [00:13:36] Hi, Dr. Chris O'Connell from Fox or Fox 29 here in Philadelphia Probably cross town from you, go birds! You know, as a science, I'm literally sitting here as we speak, looking at the White House press conference. You know as a scientist, how do you reconcile the fact that patients may be getting mixed messages from the science community and then the White house? I mean, from, I mean President Trump saying today, taking Tylenol is not good for pregnant women. He said that no less than three times. How do you reconcile? What should patients be wondering tonight?

Dr. Brian Lee, Drexel [00:14:19] I think you bring up an excellent point. Any time a different voice is added to the conversation, it causes a bit of confusion, especially if the messaging is completely different. And you've seen this with vaccines and the recent advisory committee decisions on the MMR vaccine, for example, and it's the same sort of chaos that's being introduced here with science. To date, acetaminophen remains the safest alternative for pain relief medication, and it's unclear what exactly would replace that if this were somehow regulated in a way that, or pregnant women were advised to stop using it. It's an excellent question.

Sara Whitlock, SciLine [00:15:15] Thanks so much for asking that. And I wanna remind reporters on the line that if you do have a question, feel free to raise your hand and we will call on you in that order. Right now, I want to ask a question about what you think that reporters should know or pitfalls they should avoid, Dr. Lee, as they're covering these claims coming out of the White House.

Dr. Brian Lee, Drexel [00:15:35] I think there's a lot of... There's a lot of evidence being spouted. And as far as the quality of the evidence, let's just say that the quality isn't necessarily all high quality. And scientists like me are trying to cut out some of that noise, but it's an incredibly difficult decision and task for folks to understand this. I think what people should take away from all of this is that physicians remain the sort of the keystone in terms of being the best source of information because they are the ones who have to process the scientific information. The average American out there shouldn't have to deal with that responsibility. So talk to your physician if you have questions. And ask questions, I think that's the number one recommendation. But the bottom line so far is that unless there's new evidence that's coming out to say otherwise, the expert clinical bodies out there do not have any, do not find any strong reason to believe that Acetaminophen causes autism or ADHD.

Sara Whitlock, SciLine [00:16:59] Thank you. And we have a question from Ari Hait. Ari, if you can say your name, outlet, and question, please. We aren't quite hearing you yet, Ari. I'll give one more minute for Ari and otherwise we will move on to our next question, or Ari you can type your question as well if that would be helpful. Until we hear from Ari, let us go on to the next question and that is from Karen Wright. Karen, if you can say your name, outlet, and question.

Karen Wright, KMSU Minnesota [00:17:42] Karen Wright from Minnesota Independent Public Radio. And my question is how has what's been being done with the cuts to CDC and all these other cuts been affecting your research and other research related to science and how it's gonna impact what's, I guess, the information that we're finding or not finding out because it's, I guess it's not being done because I know it, I'm at a university and a lot of the grants and things have disappeared. So how is that impacting you as a scientist and others?

Dr. Brian Lee, Drexel [00:18:18] That's an excellent question. And, you know, we try and keep politics out of science as much as possible, but certainly this chaos from above has filtered down to the university level and funding disruptions and cuts have been extremely disruptive. And it's difficult to pretend that this hasn't affected the science that we do on a day to day basis so you know, I've had it better than other colleagues who've had their funding completely cut off or have lost jobs, but you know I think any upstream effect to the NIH or CDC is going to filter downstream to not only researchers but the communities that they serve.

Sara Whitlock, SciLine [00:19:05] Thank you. So what do we know about the genetic drivers of autism and how strong is the body of evidence for those causes?

Dr. Brian Lee, Drexel [00:19:12] So the genetics for autism is a complicated topic, but what we do know on a very basic level is that a lot of autism is familial in nature. So for example, if you have a set of identical twins, the probability that if one has autism that the other has autism is extremely high. It's not 100% high, but it's very high. And from anecdotal observations like that to more larger genetic studies, we are starting to have a clearer picture that there are certain very strong single genetic mutations that predispose to autism risk, but that there also are hundreds or if not thousands of other smaller genetic variants that are contributing to risk. So the long story short is that this is not a monogenic condition, but rather much like other complex conditions like human height or depression, there are a large number of contributing genetic variants. And we're hopeful that the next studies out there are going to shed more light on this.

Sara Whitlock, SciLine [00:20:35] Thanks so much. Our next question is from Martin Davis. So Martin, if you can say your name, outlet, and question, please.

Martin Davis, Fredricksburg Advance [00:20:47] Martin Davis from the Pettisburg Advance, local media company outside of Washington, D.C. One of the things that I hear very often is that critics who back what the president is saying today will point out that autism rates in the U.S. are much higher than they are in Europe. What do you know about that and how would you explain that?

Dr. Brian Lee, Drexel [00:21:15] I happen to do research in Sweden, and the rates there are quite high. But in general, any time you have discrepancies in disease or disorder, or any sort of conditions between countries, it's easy to hypothesize factors that might be different between the countries. But for something like autism that has such a high genetic

component to it, we would expect to see that the prevalences are going to be roughly the same where you are after you account for different things like different diagnostic systems and what have you. So earlier in the press conference, I think President Trump mentioned that the Amish have no autism. And that's not necessarily the most credible claim. If there were any data to support that, well, what's more likely to happen is that, people who might be Amish are going to be less likely to seek medical care, which also would result in less chance at getting an autism diagnosis. So these sorts of things are at play and it's not really easy to just point the finger at, say, oh, this country or this community has higher prevalence because there are other factors contributing to the higher prevalence.

Sara Whitlock, SciLine [00:22:43] That makes a lot of sense. We're gonna go back to a question that we got a little bit earlier from Ari Hait. They are a reporter at WPBF ABC 25 in West Palm Beach. Their question is related to what we were just talking about and it is that the president mentioned that there are no cases of autism in the Amish community and in Cuba. He says that's because they don't have access to Tylenol, can you address that and is that true?

Dr. Brian Lee, Drexel [00:23:07] To the best of my knowledge, I haven't seen any evidence to support that, these assertions and as I mentioned before, there are a lot of contributing factors to whether or not prevalence of autism is higher in one community than in another, and things like access to healthcare, access to autism diagnostic services, is going to play a large role in whether or not there is going to be a higher prevalence in a community or not.

Sara Whitlock, SciLine [00:23:42] Our next question is from Kamilah Williams. Kamilah, if you can go ahead and unmute and say your name, your outlet, and your question, please.

Kamilah Williams, WTKR 3 Norfolk [00:23:52] Hi there, I'm Kamilah Williams with WTKR News 3 in Norfolk, Virginia. My question is, could this information now contribute to the increase in maternal mortality rates and the trust people have in this now new recommendation.

Dr. Brian Lee, Drexel [00:24:18] I can't speak about maternal mortality, but what I will speak about that is it's almost certain that this is going to cause a lot more confusion when you're receiving fragmented and dissenting messaging from our public health officials. And so again, this is where I would hope that personal physicians are able to cut through that noise and help their patients. Receive the best care that they can get.

Sara Whitlock, SciLine [00:24:52] Thank you. Our next question is from Shelley Schlender. So Shelley, if you could unmute and again say your name and your outlet before you ask your question.

Shelley Schlender , KGNU Boulder [00:25:00] This is Shelley Schlender from KGNU Boulder, Denver, Colorado. You indicated that genetics are a big factor in autism. What influences the genetic expression? What are factors that are known like? Are there medications that do increase the risk of autism if a mother takes them while she's pregnant? Are their factors about somebody having certain other illnesses? Are there other things that you can say are in the environment that affect whether or not someone with a genetic predisposition is more likely to have autism?

Dr. Brian Lee, Drexel [00:25:38] That's an excellent question. And in general, what I'll say is that for complex disorders, for example, heart disease, it's very rare that you can just

say that, oh, this example of heart disease is going to be caused by X, Y, or Z genetic mutation. We know that genes don't live in isolation. We are exposed to genes, our genes, we are expose to the environment. And the joint contributions of these two is something that hasn't been necessarily well-studied. So I think this leads to the larger point that just because our study and others have found no credible evidence to support that acetaminophen causes autism or ADHD doesn't mean that the door is closed on scientific inquiry. I mean, the example I often use is everyone knows that smoking causes lung cancer, but that's not to say that that line of inquiry is completely shut. We know that some folks can smoke two packs a day for 20 years and never come down with lung cancer. Why is that, right? And it's something about their individual physiology, their genetics that might be protecting them. And so these are the kinds of scientific inquiry that I hope that discussion like what came out today would foster and not necessarily any more sort of You know false messaging like along the lines that oh vaccines are causing autism.

Sara Whitlock, SciLine [00:27:11] Thank you. And we have another question from Karen Wright. If you could again say your name, your outlet, and your question.

Karen Wright, KMSU Minnesota [00:27:18] Karen Wright, KMSU in Minnesota. So why acetaminophen? Why not naproxen or ibuprofen or things like that? I mean, they're similar painkillers. So why not distinguish that from acetaminophen?

Dr. Brian Lee, Drexel [00:27:34] Yeah, that's an excellent question. So, you know, acetaminophen is one of the most widely used, if not the most, widely used pain medication in households today. And so just because of that sort of prior, there's more sort of emphasis on that, but there are... You know, NSAIDs are associated with a number of adverse developmental outcomes, and there's a reason that it's contraindicated. In other words, there has been messaging that pregnant persons should not be taking NSAIDs. But one of the things I'd actually like to point out in our Swedish study was that we did look at NSAIDs as well and found the same sort of, you know, small statistical effect, association that NSAIDs were associated with increased risk of autism and ADHD when you did the apples-to-oranges comparison, but when you do the apples-to-apples comparison looking in siblings, again that went away. I think the bottom line though is that a lot of medication used during pregnancy, that the safety profiles haven't necessarily been well established in human populations, and so there's certainly a lot of room for additional research in this area.

Sara Whitlock, SciLine [00:28:57] Thank you and related, but taking maybe a little bit of a step back, can you characterize the overall body of literature on Tylenol and autism? How much research has been done? Is this an area of widespread scientific consensus? And if not, what would it take to get there?

Dr. Brian Lee, Drexel [00:29:11] Yeah. So as far as acetaminophen and autism goes, I believe the first sort of study on this topic came out in 2014. This was a study out of Denmark, roughly 50,000 folks, give or take. And they found the same sort of small statistical increase in risk associated that we found initially. But these sorts of studies, I believe that 2014 study or 2015 study was the largest to date on the topic until our study came along. And sample size is not everything, but one of the things that we were able to do in our study was this sibling control analysis. And so our study was not the only one to do this sibling control analysis, but a sort of consensus is emerging that for the studies that are actually controlling for genetics and familial confounding, those studies are not supporting that a causal association exists between acetaminophen use and autism. Whereas the sort of apples to oranges studies just looking at folks who use versus folks

who don't use, they're finding the small increase in risk. I think that basically summarizes the state of the human evidence.

Sara Whitlock, SciLine [00:30:45] Sounds great. Thank you. And we have another question from Shelley Schlender. So Shelley, if you can go ahead and say your outlet and your question.

Shelley Schlender , KGNU Boulder [00:30:54] Yes, thanks again. This is Shelly Schlender from KGNU Boulder, Denver. I'm just trying to follow up, do the Venn diagram thing, see where things intersect. Are there some medications that have been tested where you definitely are likely to say, these are ones that you probably shouldn't take when you're pregnant because they might increase the risk of autism or ADHD? Do you have some medications like that that you might be able to name?

Dr. Brian Lee, Drexel [00:31:21] Yeah, there is one medication in particular that our team and a number of other research teams around the world have identified as being consistently associated with increased risk. And that is sodium valproate, which is an anti-seizure medication. So valproate, for short, is a medication, you know, used to treat seizures or epilepsy, and it actually has a long history of being associated with birth defects. So, you know the warnings already exist for women of reproductive age to avoid using that if at all possible. But, you know, before I keep rambling on, I'll just say that's an example of one medication that has been credibly linked to increased risk of autism.

Sara Whitlock, SciLine [00:32:19] Thanks for that context. A pediatrician at today's White House briefing said that most mothers will not need Tylenol at all during pregnancy and only a very small percentage needed it. In your research, do you know what percentage of pregnant people take Tylenol?

Dr. Brian Lee, Drexel [00:32:35] So the number of people that take Tylenol is going to differ by the population that you examine. So various studies have looked at this and defined usage in different ways. Our study looked in Sweden and found roughly 7.5% prevalence in use. Sweden's a very different context from other populations. In the U.S., it's been estimated anywhere from say 50 to 70%. A large part of this is discrepancy can potentially be due to differences in definition, in addition to differences and who you ask, but differences in definition might include, for example, you know, how you define use. If is use though the one time thing, or is use going to be a regular thing. So for example, you know, I technically am a drinker of alcohol, but I drink maybe once a year. Is that enough to classify me as a user? And this is going to differ on the context that I'm answering. And so these sorts of definitions are going to different. And so yeah, in short, the prevalence of use of acetaminophen is certainly going to be widespread around the world, but the exact numbers are going to differ.

Sara Whitlock, SciLine [00:34:04] Thank you. And I want to remind reporters on the line that if you would like to ask a question, please raise your hand so you can ask your question verbally. I see that we have some in the chat. While we're dealing with that, I want ask a question about funding for research. The White House has announced it will provide additional funding for research on autism causes. If you were given the opportunity to direct those funds into particular areas of research, Dr. Lee, what do you think would be the most promising?

Dr. Brian Lee, Drexel [00:34:30] Oh, that's an interesting question. So, you know, I'm actually fortunate enough to be participating in a few ADSI awards that were announced

today. So one, for example, one such award is being led by my colleague at Drexel, Dr. Kristen Lyle, who's examining the diet during pregnancy, diet and nutrition during pregnancy and child autism. And I think that's a fantastic use of these resources. And another award I'm fortunate enough to participate on is led by Dr. Jonathan Sabat of UCSD. And it's looking at the combination of genetics and environment leading to potential increases in autism and these sorts of efforts I'd like to highlight are um I think necessary studies to do um and they we haven't necessarily uh been able to secure funding for these so you know uh keeping politics out of the conversation I'm glad that there has been renewed interest as to the causes of autism.

Sara Whitlock, SciLine [00:35:43] We have our next question from Stephanie Innes. So if you can unmute and say your name, outlet, and question, please.

Stephanie Innes, Arizona Republic [00:35:49] Hi, my name is Stephanie Innes and I'm a reporter at the Arizona Republic in Phoenix, and the FDA just announced that they are initiating a process for a label change on acetaminophen to reflect what they say is evidence suggesting that the use of acetaminophen by pregnant women may be associated with an increased risk of neurological conditions such as autism and ADHD in children. Is there enough evidence, in your opinion, to warrant such a label on acetaminophen?

Dr. Brian Lee, Drexel [00:36:25] Unfortunately, I can't comment on the FDA process myself because I don't know what sort of processes are going on behind the scenes to, you know, to lead to that conclusion. But what I will say is that, you know, our study and others have indicated that this causal association does not exist. And certainly someone else can find evidence to the contrary, but I believe that our studies that do take into account genetic confounding are the highest quality today. And our study, as well as others that have done the same thing, find no evidence to support this possible association.

Sara Whitlock, SciLine [00:37:12] Thank you. Our next question is from Claire Bugos. So if you can unmute and say your name, outlet, and question, please.

Claire Bugos, Verywell Health [00:37:20] Hi, I joined late, so I apologize if this was already asked. I'm Claire Bugos from Very Well Health. Given that in your trial, the reported acetaminophen use was in about 7.5% of participants, which is much lower than the reported use in pregnant people, certainly in the US, and my understanding is in biomarker studies in Sweden as well, I've heard arguments that could bias the null or that there, you know, I've heard from people who think that there is an association that the low reported use of acetaminophen in that trial could have sort of biased the results. What do you say to that? And do you have any perspective on whether people accurately self-report or understand their acetaminopen use? I know a lot of people know it as an active ingredient in Tylenol. Are there other medications that people should be aware of? If they're trying to understand whether or not they use acetaminophen.

Dr. Brian Lee, Drexel [00:38:19] Yeah, certainly. These are excellent questions. So I'll start, first of all, just a small note, this is not a trial. This is an observational study. So we're just following the data and not experimentally administering Tylenol to one group and not the other. So just that small clarification. So our study had a lower prevalence of acetaminophen use, but the the critics are suggesting that that is somehow responsible for our null results. I'd like to point out that we started on the exact same footing. So when we did it the apples to oranges way, the standard way that everyone did, we found the exact

ballpark of numbers, like the one point, you know, hazard ratios of 1.2 to 1.3, which is exactly in line with the other studies that have supposedly found an association, but so it's not, the lower use in our sample does not in any way bias our results. And so starting on that foot, we then showed that the sibling analysis completely eliminated any possible associations. So yeah, in short, the low use in the sample was not a reason for our null findings. Um, and then I apologize. I missed the last part of your question.

Claire Bugos, Verywell Health [00:39:53] Um, the second part of the question was about acetaminophen in drugs that are not Tylenol and people's understanding of their exposure.

Dr. Brian Lee, Drexel [00:40:02] Sure, and that's a very fair point. Acetaminophen is an active ingredient in over 100 different medications, so it's very possible that people are using it but are not aware. One of the things that our study did was actually looking at prescription medication use of acetaminophan, so actual medical dispensations of it, and we found the exact same thing as we did with the self-report. You know, in aparent statistical association, but it goes away when you do the sibling analysis.

Sara Whitlock, SciLine [00:40:36] Thanks so much. We are almost at time. So Dr. Lee, I want to give you a chance in 30 seconds or so to leave us with one take home message you like reporters on the line to remember.

Dr. Brian Lee, Drexel [00:40:47] Yeah, I think after today, the messaging about acetaminophen shouldn't change anything. You know, the advice has always been lowest dose possible for as short as possible. And I think, you know, that probably still stands. But ask your doctor, and hopefully the doctor is checking with the expert clinical bodies about recommendations, and, hopefully, good information will come to any pregnant person who's seeking it.

Sara Whitlock, SciLine [00:41:16] Thank you so much. We're at time now, so we're going to conclude the press briefing, but we wanna thank Dr. Brian Lee for sharing your expertise. We really appreciate you taking time to share with us today and to the reporters who are on the line, thank you so much for joining and for asking your questions. Please keep an eye on your inbox for two different emails tonight, one with the video recording of this briefing and one with a transcript. Take care, everyone.