

CRIB BUMPERS MEETING

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

201 West Preston Street
Lobby Room 2
Baltimore, Maryland 21201

Friday, May 20, 2011, 3:00 p.m. - 5:00 p.m.

ATTENDANCE:

Dr. Joshua Sharfstein, Secretary, Department of Health and Mental Hygiene

Dr. Marsha Smith, Department of Health & Mental Hygiene

PANEL

Dr. Peter Beilenson, Health Officer, Howard County Health Department

Dr. Tina L. Cheng, Professor of Pediatrics and Public Health, Johns Hopkins School of Medicine

Dr. Gaurov Dayal, Chief Medical Officer, Adventist Healthcare

Dr. Joseph Wiley, Chairman of Pediatrics, Children's Hospital at Sinai

Transcribed by Carol O'Brocki in association with
Hunt Reporting Company of
Glen Burnie, Maryland

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P R O C E E D I N G S

(The meeting commenced at 3:08 p.m.)

DR. SMITH: Okay, good afternoon. This is Dr. Marsha Smith, and I want, I am Director of perinatal and reproductive health, with the Department of Health and Mental Hygiene, Center for Maternal Child Health.

I'd like to begin by welcoming the panel on behalf of the Department and the Secretary to this meeting of the Advisory Panel to review the use of crib bumper pads in infant cribs.

Just as background, as you know, bumper pads are pieces of cushioned lining designed to be attached to the side of an infant's crib for the purpose of preventing the infant from bumping into the crib.

The Secretary of the Department of Health and Mental Hygiene requested comments from members of the public, interested parties, health professionals, and persons knowledgeable about product safety concerning

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the use of bumper pads in infant cribs. The Secretary has appointed this advisory panel to review comments received, and to consider available relevant information documenting the risks and/or benefits to infants associated with the use of crib bumper pads.

The purpose of today's meeting is for the panel to advise the Secretary as to what action, if any, is warranted. Specifically, there are several issues for which the Department would like recommendations from the panel. The panel will determine the risks and benefits, if any, to the use of crib bumpers to determine if the Department should provide input to the Consumer Product Safety Commission in it's review of the safety, in it's review of safety products and the content of these warnings to consumers; determine whether crib bumper pads should be considered a hazardous material, and if so, should the Department of Health adopt regulations addressing the sale, marketing, or labeling of bumper pads.

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There has been a period of public comment on these issues. That comment period ended on May 9. Public comments have been posted on our website and made available to the panelists.

This meeting is open to the public. The public may attend in person or call in to observe the panel process. This is not an additional opportunity to submit comments or to address the panel directly.

I would like to remind the experts participating on the panel that this meeting is being recorded. A written transcript of today's meeting will be available on the Department's website. Please be mindful of this during all discussions, as some of the individuals who have submitted comments have requested that certain information not be made public.

Now let's move on to introductions. I'd like each panelist to state your name, your title, and answer the conflict of interest questions. It is recognized that each person is participating in their

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own capacity and is not a representative of an institution.

I'll begin with the panelist to my right, and I would like you to wait until, I would like you to state your name and your title, and then answer after I read each question. Okay. You may begin.

DR. WILEY: Okay, so I'm Dr. Joe Wiley. I'm the Chairman of Pediatrics at the Children's Hospital at Sinai.

DR. SMITH: Okay. Do you have or any immediate family member have an ownership interest in any organization or commercial entity with a direct interest in the matters you will be discussing today?

DR. WILEY: I do not.

DR. SMITH: Are you or an immediate family member employed by any organization or commercial entity with a direct interest in the matters you will be discussing today?

DR. WILEY: I am not.

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DR. SMITH: Are you aware of any reasons why you could not participate impartially in today's discussion?

DR. WILEY: No.

DR. SMITH: Thank you, Dr. Wiley. Next panelist, please?

DR. DAYAL: I am Gaurov Dayal. I'm the Chief Medical Officer of Adventist Healthcare based in Rockville, Maryland, and I'm also a pediatrician.

DR. SMITH: Thank you. Do you or any immediate family member have an ownership interest in any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. DAYAL: No.

DR. SMITH: Are you or any immediate family member employed by any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. DAYAL: No.

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DR. SMITH: Are you aware of any other reason why you would not participate impartially in today's discussion?

DR. DAYAL: No.

DR. SMITH: Thank you. Next panelist?

DR. CHENG: Tina Cheng. I'm a professor of pediatrics and public health at Johns Hopkins University.

DR. SMITH: Thank you. Do you or an immediate family member have an ownership interest in any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. CHENG: No.

DR. SMITH: Are you or an immediate family member employed by any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. CHENG: No.

DR. SMITH: Are you aware of any other reason

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why you could not participate impartially in today's discussion?

DR. CHENG: No.

DR. SMITH: Thank you, Dr. Cheng. Next panelist, please?

DR. BEILENSON: I'm Peter Beilenson, I'm the Howard County health officer.

DR. SMITH: Thank you. Do you or an immediate family member have an ownership interest in any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. BEILENSON: No.

DR. SMITH: Thank you. Are you or an immediate family member employed by any organization or commercial entity with a direct interest in the matters you'll be discussing today?

DR. BEILENSON: No.

DR. SMITH: Are you aware of any other reasons why you could not participate impartially in

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today's discussion?

DR. BEILENSEN: No.

DR. SMITH: Thank you, Dr. Beilenson. I'd like to now introduce the Secretary of the Department, Dr. Joshua Sharfstein.

SECRETARY SHARFSTEIN: Hello. Good afternoon. Thank you all for coming. I appreciate your taking time from your, you know, extraordinarily busy schedules to come and help us think about this issue and provide input.

I wanted just to mention a few things. The first is that there are absolutely no presumptions or assumptions that I bring to this discussion. I think we raised this as an issue because of concerns that have come up and we wanted to get public comment. We've shared them with you, but there's absolutely no plan or thinking on our part of where we would go. At this point we would like to understand what you think of the evidence and what you would recommend, and

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second of all, that I have, with three pediatricians and one public health professional on the panel, I'm asking the public health professional, the one who's not like the others, to be, to kind of organize the group and keep it kind of, keep things moving through the questions. So you can have time to discuss the science and then discuss what you think the recommendations would be for the Department, and then whenever you're done, we're done, so we're not stuck here until 5:00.

Whatever you think, and we're going to turn it over to you and really to provide us with your best input. We really turn to you because each of you brings different and very helpful background to these issues, and also because each of you has demonstrated terrific judgment in a lot of different areas. So we really appreciate your willingness to spend time with us.

And we will say that, you know, I'm going to be

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here. We're not going to interject, though. If you have questions for me about anything, you can, you should feel free to ask me or Dr. Smith, but really this is an opportunity for you all to see what you think makes the most sense, and for the Department, give the benefits, potential benefits, potential risks of these products.

Do you have any general questions for me at this point?

(No response.)

DR. SHARFSTEIN: No?

DR. SMITH: Okay?

DR. SHARFSTEIN: Okay.

DR. SMITH: All right. So, we have an agenda for you today as Dr., thank you, Dr. Sharfstein, has mentioned. There's a break but if you choose not to take it you can work through. I'm just going to read the questions which have already been provided to you.

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The first question is, please discuss as a group the published research presented to the panel.

Question A: Does the evidence support a finding that the use of crib bumpers provides benefits to infants.

Please explain your --

DR. SHARFSTEIN: Can I make one comment?

DR. SMITH: Yes, sure.

DR. SHARFSTEIN: And I'm sorry about this.

For this, I think, we're interested in the published research as well as the public comments, and just, you know, just all of the materials that you have. Sorry, Dr. Smith.

DR. SMITH: No, that's okay.

DR. SHARFSTEIN: And we could just add, and public comments. You know, other materials that you have. So it's really everything we're interested in, in your sense of.

DR. SMITH: Okay. And Question B: Does the evidence support a finding that the use of crib bumper

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pads poses a substantial risk to infants? Yes, please explain your reasoning. If there is concern, Number 2, if there is concern for risks to infants, please discuss as a group whether labeling is a possible solution.

Question C: Could improved labeling mitigate the dangers associated with the use of bumper pads in infant cribs? Please explain your reasoning, and if yes, please suggest the type of labeling you would recommend.

Number 3, the Consumer Product Safety Commission is in the process of considering the safety of bumper pads.

Question D: Should the Department provide input to the CPSC on crib bumper pads, and if so, what should that input be?

Number 4. One option for the Department is to issue a warning to consumers.

Question E: Is a warning to consumers about the

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use of all or certain bumper pads justified, and if so, what do you recommend regarding the content of that warning?

Number 5. The Department can regulate hazardous materials, defined as, defined in part as a toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard.

Question F: Should the Department pursue regulations that define crib bumpers as hazardous materials?

Question G: If so, should those regulations address the labeling of bumper pads? Please provide specific recommendations, if applicable, or refer to your answer in Question C, if appropriate.

Question H: If so, should those regulations address the marketing of bumper pads, please provide specific recommendations, if applicable.

Question I: If so, should those recommendations address the sale of bumper pads? Please provide

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specific recommendations, if applicable.

Again, I want to remind you, I'm sorry. Do you have a question?

DR. BEILENSEN: Yeah. Are any of these mutually exclusive, we could say yes to all of them, or no to some, and yes to others; and do you have the power to, how far can you go? Can you actually prohibit the marketing of these things in the State of Maryland if they're, if hypothetically, if the group decided it was hazardous material, how far can you go on all of these things?

SECRETARY SHARFSTEIN: Sure. So you could answer these questions however you want. In fact, if you think they're not the right questions, you could even change the questions. This is really where, our starting place, but it's really, we want you to be able to provide input the best way you think possible.

For hazardous material, under the regulation, we could ban them. The sale.

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DR. SMITH: There's an actual, there's a reference that we've included in your packet.

SECRETARY SHARFSTEIN: And maybe you can have just a walk through what's available so you know what you have in here.

DR. SMITH: Right. You have all the documents that were sent.

SECRETARY SHARFSTEIN: So let's just go through them.

DR. SMITH: In terms, we have the comments, Comments 1, 2, 3, 4, 5, 6, 7, 8, 9, and again be mindful that this meeting is being recorded, as some of the individuals have requested that certain information not be discussed in public. So the format that you have is the one, the content.

SECRETARY SHARFSTEIN: Right. All that is is their personal information. Right.

DR. SMITH: Right. Exactly. Exactly, and then you have the list of documents that were provided

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and those are on our website. The testimony of H. Gary Gardner (phonetic). You have the article entitled, *Infant Sleep Environments Depicted in Magazines*.

The, No. 3 is Sudden Infant Death Syndrome prevention. No. 4 is entitled, *Things that go Bump in the Night, Nothing to Fear*. No. 5 is *A Qualitative Analysis of Beliefs and Perceptions about Sudden Infant Death Syndrome*. No. 6 is *Deaths and Injuries Attributed to Infant Crib Bumper Pads*. No. 7 is *Injuries Associated with Cribs, Playpens, and Bassinettes Among Young Children*. No. 8 is *Agency Fails to Probe Deaths Linked to a Popular Baby Product*, which was a newspaper article. No. 9 is another newspaper article with the title, *Deaths and Bumper Pads*. No. 10 are, a policy statement by Health Canada regulations regarding crib bumper pads and warnings issued to consumers, and No. 5 is a letter that was received by the Office of the Chief Medical

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Examiner. Those are all the items --

SECRETARY SHARFSTEIN: It was sent by the Office of the Chief Medical Examiner.

DR. SMITH: I'm sorry. I said received and not, yes, sent by. So those are all the items for, under resources. I've provided a copy of the Maryland Register notice so that you are familiar with the language that was included. There's pictures of some of the crib bumper pads, then in the back, items that are for sale in Maryland. There's a copy of the Annotated Code of Maryland, Title 22, Poisonous Dangerous Hospital Substances, Flammable Products and Hazardous Materials, and also a copy of the regulations regarding family child care and healthcare facilities on soft bedding items.

You have a copy of the questions, and space has been provided to you if you would like to take notes, and there is also an agenda.

SECRETARY SHARFSTEIN: Let me just thank the

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sanitarians of Howard County who took the pictures of the bedding for sale, and also, thank you, Dr. Smith for organizing this.

DR. SMITH: You're welcome. So again, please be mindful that this meeting is being recorded. We would now like to turn it over to the panel for discussions. I believe we've all agreed, and you've agreed not to take the break and to just go through the discussions, and then your own review of the questions, and then at, what time do we have now? We have 4:05 on the agenda. We'll, whenever you're finished, then you can report back to us with your recommendations. I'm sorry, to the Secretary, not me.

SECRETARY SHARFSTEIN: And we will keep you posted about what the time is, and it's up to you about breaks, too.

DR. BEILENSEN: You're just sitting here though, right?

SECRETARY SHARFSTEIN: I'm just, --

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DR. BEILENSEN: I mean, you're still here.

SECRETARY SHARFSTEIN: I'm here.

DR. BEILENSEN: Well, welcome. What's your last name again?

DR. DAYAL: Dayal.

DR. BEILENSEN: Dayal, yeah. Dr. Dayal, Dr. Wiley, and Dr. Cheng. Well, you guys are the experts. You're all pediatricians, and we saw the information that's been published to date. So the first thing we're supposed to do is discuss as a group the published research presented to the panel. There are a couple of major issues. Number one, are there, is there any evidence, and this weeds through the various questions, is there any evidence that bumpers actually help in terms of safety of infants in a crib, in terms of preventing injury, et cetera, number one; and number two, what do you think of the evidence of the dangers of crib bumpers? I'd like to start with whoever wishes.

Comment [m1]: Should be "weaves"

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DR. WILEY: So dealing with Question A, does the evidence support the finding that they provide benefits? I'm not sure that I read any evidence that actually was done in any kind of scientific manner that actually looked at safety or benefit. I think most of what I've read, either by public comment or by published literature has been either dealing with the risks of bumpers, or trying to refute the risks of bumpers.

There are a large number of statements talking about the risk of injury to infants in a bed, and that the bumpers could potentially "prevent injury to their extremities, to their head", et cetera, et cetera.

The problem with a lot of that data, and there's a really nice publication by Linear (phonetic) about a very large database looking at injuries in cribs, and there's really no way to control for or even account for the impact, because no one's looked at separating out who had bumpers and who didn't. So I didn't find,

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and I've asked the panelists if they agreed, I did not find any evidence that someone had carefully looked at the distribution of injuries in cribs that were reported either through an emergency room situation, or through any other situation in which they separated out the injuries by whether or not they were bumpers or not bumpers.

In addition, I think that some of the statements by many investigators overstating the risk of no bumpers in the era of a small slat opening I think was overstated. I mean, we talked about this in advance a little bit right here is that the issue of fractures. The risk of a fracture of an infant, under six months of age in a bed situation is highly unlikely, and actually brings to light maybe that there are other reasons why that fracture occurred.

DR. BEILENSEN: All three of you are practicing pediatricians, right? Have you ever, I understand this is anecdotal evidence, not necessarily

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statistical, but have any of you ever seen an example of an injury to a child in a crib without bumpers, due to the hitting of the slats too hard?

DR. WILEY: So you asked two separate questions. Have we ever seen injuries in a child in a crib without bumpers? Yes. How do we know that they were not due to other issues? Most of the time, I would say the vast majority of the time, they've raised the issue of intentional injury, rather than unintentional injury. I've never seen any child injured, and I think we have to be careful about, you know, what we have seen, because, you know, if you look at the data that's published, the likelihood of a severe injury or the death is really quite rare, even in a situation where the risk might be greater with one set of circumstances versus the other.

And I think that's really important because, you know, there's a lot of public comment. People talk about, you know, no one I know has ever had a problem.

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No one's ever had a death. The incidence is pretty low. It's probably in the neighborhood of one in 100,000, around that, per death, and a little higher, maybe one in 10,000 or a little higher for injury. So unless we all know hundreds of thousands of instances, we may not have enough personal experience to really say, but yes. I've never seen an injury that I can say was sustained by a non-bumpered crib.

DR. BEILENSEN: Dr. Dayal, maybe not the same question, but how do you feel about those two general questions?

DR. DAYAL: I would agree with Dr. Wiley. I think some of the, some of the articles had a suggestion of a possible link between injury and injury prevention using bumpers, but there was no scientific evidence. And, to be fair, we also didn't have an article that looked into that, so it could be that --

DR. BEILENSEN: What kind of injuries would

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possibly, say you've got a little four month old.

What could happen to her?

DR. DAYAL: I think that's a great point.

Some of the authors and I think the Thach article references that the amount of force needed to, for a four month, a four month old cannot generate enough force to create a self-inflicted fracture or a closed head injury, which are the two injuries that we would be concerned about and that the bumper is supposedly preventing.

So I think it, one of the AAP articles did reference the fact that there's a possible benefit of minor injury prevention using bumpers. It wasn't fully discussed. It wasn't one of the references, I think.

DR. BEILENSEN: What about devil's advocate? A crib falls, a dog runs and knocks the crib over, there's bumpers on the crib versus no bumpers. Is there any kind of protection for the baby? Just

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asking.

DR. DAYAL: How big's the dog?

DR. WILEY: No, if the crib falls over, the bumper's going to be, you know, it's like putting a pillow and dropping somebody from 10,000 feet. It's really not that --

DR. DAYAL: And I think that Dr. Wiley's other excellent point is the law of numbers. So even in worst case unfortunate situations, we are luckily looking at, we find that number, even if those numbers are off because of, which has been referenced in the articles that reporting systems are different, that we don't know what the accurate numerator and denominator are. But even if we're off by a factor of ten, it's still luckily not a huge number, but the issue becomes one of risk versus reward. What is, what is, if the benefits are questionable at best. The risks seem fairly concrete based on the, in small numbers, but based on the data presented, the risks do seem much

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more concrete, so I think a lot of it becomes which is more important, and I do think that at least two or three of the articles referenced the fact that, to your point, that the four month, six month old infant is unable to, unable to self inflict injury to that level, and I think it raises to your second question, if we ever do see that, sure, we see a lot of kids injured --

DR. BEILSENON: If you see slat marks on a kid's leg, it's very likely from some kind of adult doing something, and not actually the child.

DR. DAYAL: Correct, and I think, right, I think that's what we were talking about earlier, that any time we see any injury in a four month old, actually regardless of where they were in a crib or out of a crib, it's something that has to be investigated.

DR. WILEY: And I think, just one last thing and then Tina's probably ready to jump in here, but

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the one thing that I think that's really important is when you read all of this literature, all of the comments, nowhere does it ever suggest that an unprotected crib, in other words, a crib without bumpers, ever results in an injury severe enough to cause death.

DR. DAYAL: Yet the discussion is really around the fact that we are concerned that the use of bumpers may increase. And so a lot of the debate is whether or not, you know, there are deaths associated with the use of crib bumpers. Whether that's causal or not, that's what we're here to discuss. But nowhere does anyone suggest that the lack of crib bumpers leads to a fatal event. Dr. Cheng?

DR. CHENG: I mean, yeah, I would agree with most of what's been said. I think that there isn't strong evidence to support finding that the use of crib bumpers provides any benefits to infants. I think that the benefits we are talking about is some

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kind of injury related to hitting your head against, you know, against the crib slats. Thought it's, you know, it's possible that there is some benefit that there hasn't been research on this issue, though I think as we've discussed, the mechanism of injury would have to be fairly odd for a four to six, for a child of that age to really have an injury.

I think the evidence regarding the use of crib bumpers posing a substantial risk, you know, we've read the Thach article and the articles that were given, I think that the issue of risk is one of, you know, what's the rate of the risk? I think we don't have a denominator, which is too bad. We don't know how many people are using crib bumpers, and are the deaths that might be related to crib bumpers a lot in relationship to all, to how many people are using bumpers? I think we don't really have a good denominator.

And I think the numerator, I think is a difficult

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numerator to get at. The Thach article, I think, goes into certain situations where they have found that kids that were found next to a bumper, their face in the bumper, close to a bumper, I think whether that was actual causal, as the cause of death, I think is, is hard to know.

DR. WILEY: Whether the numerator was actually 27 or lower?

DR. CHENG: Right.

DR. BEILENSEN: Or higher?

DR. CHENG: Right, or higher, I think is hard to know. So I think, I think, you know, as far as Question A, does the evidence support the finding that the use of crib bumpers provides benefit, I think we don't have that evidence.

MALE PANEL MEMBER: But some of the numerator, if I remember correctly, were actually related to strangulation, that clearly was causal from the bed, from the crib bumper. Is that correct?

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DR. CHENG: Well, I think that they found some children that were tangled in the, in the --

MALE PANEL MEMBER: Yeah, in particular, three that they found that had pieces of the bumper or ties, or whatever, that were wrapped around them, and were thought to be causal.

DR. BEILENSEN: Well, to get to Question A, because I think we can probably answer that, it seems to me that there's a consensus that the evidence does not support a finding that the use of crib bumpers provides, I guess, significant benefits to infants. I guess we should explain our reasoning or the reasoning. Question B, does the evidence support a finding that the use of crib bumper pads produces substantial risk to infants? I'm sort of hearing yes, but with some qualification?

DR. DAYAL: Well, I think one question is what is substantial? Is one death substantial? I think if it were my child it would be substantial. In

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terms of a large population of X-hundred thousand babies or whatever that number is in the country, I think that just to reiterate the point we really don't know, we don't know how many people are in that crib, period, right?

We can guess. But we don't know how many babies are actually sleeping in a crib versus sleeping in a bed or sleeping on the floor, and of those, how many are using bumpers? We could potentially extrapolate that, but I think that there, I personally do think that there is a risk. I think the substantial piece I would leave to, I guess, statisticians or people like you that define what exactly, how we would define that. I personally do think, based on the evidence and the data that the crib bumpers can lead to a infant's death.

DR. BEILENSEN: To me, the biggest, just sort of skipping over to later questions, but to me the biggest issue is the risk versus the cost which would

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benefit.

DR. DAYAL: Right.

DR. BEILENSEN: There literally is no benefit. I see no way, no health benefit from any of the research that I've read, any clear health benefit, and it's simply cosmetic. So, I mean, why do people buy crib, I mean, they don't make little white crib bumper bed. The ones that sell well are the ones with flowers, and animals, and blah, blah, blah. So there's a reason that they're selling these, and so to your point, even a single death compared to cosmetic, you know, is a tragedy that could be potentially prevented. Because I see absolutely no health benefit, that I can see, for the crib bumpers. But we can get to that. So, are we writing this down?

DR. SMITH: It's being recorded, and yes, to the extent possible if you could, I mean, before speaking just identify yourself and then at the end when you do your recommendations, we'll need to just,

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we'll need to have your answers.

DR. BEILENSEN: Okay. We'll kind of go as we go along, then finalize the answers at the end. Yes, sir.

DR. WILEY: So, Dr. Beilenson, this is Dr. Wiley. So, I definitely agree with everything that everybody has said and I'm not going to come up with a side of devil's advocate. But I do think that one of the things that keeps coming up in my reading, the public, which I think is important, is their perception of what they see as a benefit. And I think what we should do is to talk a little bit about that before we, I don't want the public to think that we think that their concerns are negligent, or that their concerns are not important. But to address them in the context of what we think are risk benefit.

You know, there are a fair number of comments where people are concerned about not necessarily the risk of injury to their child, but the discomfort that

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they think that it would imply, that if they bump up against the bumper they're going to wake up and cry, or that the fact that they are crying because they're startled signifies some injury or some degree of injury. Also, the fact that many of them as we sort of alluded to earlier, your anecdotal information, how many families and children do you have to know before it really becomes a significant enough number to really have a good sense of it.

And most people don't have that, and they don't realize that in a public health situation, we're talking about the health of hundreds of thousands and probably millions of children, in which we're trying to decrease a terrible event that only occurs rarely. If this is a situation where the use of a crib bumper has some benefit for a family, we need to address why that benefit does not really add up against that tiny but substantial risk of harm to the person to which it happens.

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DR. BEILENSEN: So I recommend the A, B, C, D's of safe sleep, that last one being discussed, the issue surrounding with your patients.

DR. WILEY: So going back to it though, I definitely agree that the benefits that are proposed do not seem to really add up to anything substantial, that it's really more of a discussion and education. Maybe it's A, B, C, D, E. It's discussion then education.

So I mean education with families that, you know, if a child bumps into the crib slat, they're not going to be significantly injured and if they cry, it's simply because they're startled, and if you startle a baby they'll cry, as well, and there are ways to help avoid that. Do not put things in the bed to keep them from rolling into the slats, because then that creates a new problem that we're trying to avoid.

DR. CHENG: And that's, yeah, this is Dr. Cheng. I would agree with what you've said. I think

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we really should consider what the public perception might be of the benefits of bumpers, and I think a lot of them do feel like it probably does provide some protection for them, and I mean, having my own children, I know that they did scoot around in the crib. I was kind of surprised at how much they were able to scoot around and of course more as they got older, and if people are perceiving that their kid is, especially a big scooter and, you know, hitting their head, you know, that we don't also want unintended consequences, that okay, there's no bumper in there. Let me put a blanket in there or something else that's going to protect them.

DR. BEILENSEN: So that leads to a question, can you put, you obviously had the list of all pediatricians and family practitioners in the State, I presume. As part of the A, B, C, D, E's of safe sleep, you could put out a guidance, you know, an educational guidance that we are, let's just

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hypothetically say we decide to do something about the bumpers and here is how you should, let your parents know that this is the kind of education we want to have as part of the practice. You could do something like that.

Yes. All right, we're going to keep moving on and then we'll kind of roll with the final answers to these questions. Now, Number 2, if there is, this is Peter Beilenson again, sorry. If there is concern for risk --

DR. DAYAL: Before you move on, I just wanted to if you don't mind, add one point. This is Gaurov Dayal. Around, around the Question B that regardless of what --

DR. BEILENSEN: Hold on, I'm sorry. You don't, you don't need them to identify themselves, do you?

THE REPORTER: No. I'm identifying who's speaking so please continue on, and the microphone's

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fine right there. I can hear all of them.

DR. SMITH: Okay.

THE REPORTER: Thank you.

SECRETARY SHARFSTEIN: Okay, so and just to be clear, you are not obligated to identify yourselves each time. If it's natural, you can. I think people listening on the phone were just wondering, but they'll understand the different voices.

DR. DAYAL: I just wanted to add that the recommendations from the American Academy of Pediatrics are, let's forget for a moment that a crib bumper, have no extraneous objects in the infant's bed and the bumper does qualify as that. It's not part of the bed. And also we have to acknowledge the fact that several other governments or at least the Canadian government, the Australian government, parts of the, some of the states there have looked into this and have concluded that there is a significant enough risk to their babies, who I can presume are no

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different from ours, and that they felt obligated and they feel that they have enough evidence and proof to say that this is a substantial enough risk to them.

What's interesting is the Canadian studies shows, I think they had 23 deaths versus 27 for the U.S.

SECRETARY SHARFSTEIN: Just to clarify, the Canadian were not deaths. They were injuries, just to be clear, and there was just a request from someone, Dr. Cheng if you're, when you are speaking, maybe to speak up or move a little closer.

DR. CHENG: Yeah, I wanted to just address Question B a little bit more as well, and the issue around substantial risk. I guess I'm still having trouble knowing whether this is, how substantial this risk is. I guess one question I had was are the deaths or the injuries in Canada, were they pre or post the slat change regulation, and were some of these deaths related to that, that problem?

And I guess I wonder whether we can say it's

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really causal to the bumper pads in all of these situations. I mean, if there's actually a, a tie that's around their neck, I think that that's pretty clear. But if they were close to a bumper, I think that it's hard, and obviously when somebody finds a baby that's in distress they're going to pick them up and the scene, it's disturbed at that point.

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So I guess I'm, you know, I'm not sure how to define substantial risk and I think we definitely need more data, we need more data on, you know, the infants that have been found. Were there crib bumpers at all in the bed? We don't even have that baseline information, and I think one of the comments was that we at least should be adding that into the death scene investigation as to whether there were bumpers there at all, to try to get at that --

DR. BEILENSEN: Though if you look at the further questions, they don't talk about substantial risks. They actually talk about if there is concern for risk to infants, would you recommend the following, so let's talk about that briefly and then we can come back.

Number one, and they can kind of be looked at in a, because they are not mutually exclusive, they're a bunch of different options. If there is a concern to risk for infants, is labeling a possible solution?

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Could improved labeling mitigate the dangers associated with the use of bumper pads? I actually have strong feelings on that, but I'll open it up to the three of you first. Is labeling any kind of --

DR. WILEY: Well, I have strong feelings about it as well. I think that if you have something that can risk a child's health to the point that it can contribute to fatality and there's no label that can mitigate that, and actually I think the potential problem there is that you may actually put a family at risk, and I'll explain what I mean.

If you label something, and something does happen, then the family has to deal with the fact that they must have messed up. They screwed up, because they tried to do everything that they were supposed to do and their child still ended up dying, and the label isn't going to fix that, and I think that, you know, we're not talking about a complicated machine whereby you put things together, and if you put it together

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right it always works.

I think that the data, the way that it is explained and published, and of course it's hard to know because we don't have investigations in every home. But those of us who have been parents who've lived in the crib bumper era, know that putting those things on is fraught with, it's worse than putting a bike together on Christmas Eve, I can tell you that. They are not easy to do. It doesn't matter how many times you explain it to people. Smart people can mess it up.

And even if it's done right, I'm not convinced by what I have read that that mitigates the risk. So I don't think a label personally changes that risk.

DR. BEILENSEN: Okay. Dr. Cheng? We'll go back in another order.

DR. CHENG: You know, I think some of the commentors felt that the labeling wouldn't be as affective because a lot of people aren't necessarily

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buying a brand new bumper. They might be, you know, buying them on a secondary market and some people felt like, you know, it's not an affective way to try to really reduce risk that's there.

On the other hand I can also see how it could be thought of as an educational effort, and an educational opportunity to tell people that if they are going to use a bumper, there is a risk to it, so.

DR. DAYAL: I would agree with both statements and I don't think that labeling would mitigate the danger, because everything we buy has labels on it, and people may read them, may not. I think one of the comments was very strong, I interpret very strongly which said that when I'm buying things from a store for my baby I'm assuming that it has been approved. So this is sort of a very confusing message where we're saying there's a high risk. Let's say that the label says, hypothetically, that high risk of death from suffocation, or possible risk of death. The question

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is why are we selling that, these in the first place?

So I think that it's a mixed message, and I fully agree that if we have a label on there, then the implications on the parents who do have a problem is going to be tremendous, that they must have messed up something.

DR. BEILENSEN: Okay. Another option, so I'm hearing the labeling problem, I strongly feel that the labeling is not going to be particularly helpful, for the same reasons he did.

So I'm going to skip over to Number 3, because that's actually the one federal thing that we can potentially recommend and go to the other two possibilities that this Department could do. Should, is warning to consumers, for the Department to issue a warning, is that a valuable or effective way of warning consumers? Dr. Cheng?

DR. CHENG: So can you clarify what kind of warning this would be? This would be a --

DR. BEILENSEN: We would recommend that he

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come up with some warning that he could do a press announcement about, and then send out to all providers and I guess all households, if you really to do, no, you can send out, require that all births at hospitals put out information. There are different ways they can do it. But it would be an official warning, no offense, but I'm not sure how, my feeling is I'm not sure how effective that would be.

DR. CHENG: I mean, I think a warning about, I mean, we already have educational efforts about ABC's. I think adding the D, E that we talked about, I think that that, if that's considered a warning, I think that any educational efforts are always good.

DR. DAYAL: There's definitely no downside with further education. The question is, does it change anything and I don't think it would change any outcomes, because any message would say, let's say the message was that crib bumpers are associated with potential death of your infant. Well, what do I do

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about that? I mean, it comes back to the question, either it's safe or not safe, and I think we're sending or confusing people by saying that, yeah, it's safe but you can still put it in if you want to, pretty much.

DR. BEILENSEN: Yeah, and because it's potentially deadly although the ~~rest~~ are relatively small for death.

Comment [m2]: Should be "risk"

DR. DAYAL: Correct.

DR. BEILENSEN: But you could still put it in if you want to.

DR. DAYAL: Right. Right.

DR. BEILENSEN: Which is not a very good message.

DR. WILEY: So the issue of, this becomes a more interesting discussion because now we're actually looking at how will the public interpret. What happens from here? And, and that's why I think reading many of these websites and some that were provided and others that weren't provided that I looked at. I think that

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some people, by their discussion, have been impacted by the fact that the American Academy of Pediatrics has issued a statement about safe sleep practices, not necessarily excluding crib bumpers, that the publicity, at least in Illinois and also in Canada and then some of the other stuff that's been written, has impacted how some people have answered it. Some people still say, well, and even in the face of that I'm still going to use them. So even with warnings people will still do it.

DR. BEILENSEN: But it may be a useful thing, to some extent.

DR. WILEY: It might be a useful thing, and I think that the weight of the warning is important. I think that, you know, using the weight of agencies who are interested in the health and safety of children is far more effective than the counter-warnings from people who are going to profit from it.

DR. BEILENSEN: Well, I think, and one

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example, the ABC's of safe sleep, a huge number of people now turn their babies on their back. I think that sort of warnings, you know, education from AAP and from all other, a lot of other sources.

DR. DAYAL: I think getting back to Dr. Cheng's point is the fact that even, regardless of what action is taken, in the future there are going to be legacy bumpers in cribs, parents who had previous childs (sic) with bumpers in their crib and who may do that, so education would be very important for them.

DR. BEILENSEN: Yeah, I can tell you, we use, what was the guy who ran for vice president, from Buffalo, a congressman, football player?

DR. WILEY: Jack Kemp.

DR. BEILENSEN: I'm 51, it takes a while. We use Jack Kemp's kids', because they were friends with my parents, crib for my kids, and there were like slats like that. Anyway, neither here nor there.

The other, further down the road we can, a step we

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can take is the Department can regulate hazardous materials to find in part as a toy or other substance intended for use by children that presents a variety of hazards, should the Department so question it, should the Department pursue regulations that define crib bumpers as hazardous? If so, should the regulation address the labeling? We've actually sort of talked about that. If so, should the regulations address the marketing of bumper pads, which we get to the marketing and sale, or sale of bumper pads.

So there's a bunch of questions. Number one, the predicate question being should the Department pursue options, pursue the course of trying to declare these hazardous materials. Dr. Dayal?

DR. DAYAL: I think that, I personally think the Department should pursue regulations that prohibit the use of crib bumpers. The term, hazardous material, it seems like if that's the only option, hazardous materials, I guess, maybe from a layman's perspective

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sounds more like, I guess a toxic substance, or something.

DR. SMITH: There's a, there's a copy of the fact that actually defines the meaning of hazardous material. That's Title 22 in your packet on the, it's peach colored paper. It would be on your left hand side. Where the agenda was.

DR. DAYAL: Got it. Thank you.

DR. SMITH: You're welcome.

DR. WILEY: So I love this. There are some strong, very specific definitions, and then there's any other substance the Secretary declares to be hazardous. Sure.

DR. BEILENSEN: We have this.

DR. WILEY: That's great.

DR. BEILENSEN: The local health officers have the right to declare public health hazards, too, so.

DR. DAYAL: Using that definition, using public health hazard or, I guess the, none of the above

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but --

DR. BEILENSEN: Dr. Sharfstein, can you --

SECRETARY SHARFSTEIN: Any substance declared to be hazardous is hazardous, if that makes sense. I would support that. Again, I think that the issue is, even if, I personally, again, there's no correct answer. I think that one death is substantial risk in my mind. So using that math, I would say yes.

DR. BEILENSEN: To clarify, can you classify something as a public health hazard under this code or title, or do you have to call it a hazardous substance.

DR. SMITH: This is also under, under Section 502, it says a toy, or other substance intended for use by children that represents an electrical, mechanical or thermal hazard, or needs to be declared a hazardous material to remove any uncertainty as to whether it is a hazardous material.

DR. DAYAL: Right, and this was referenced in, I think, the question itself when we got it. My

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concern around that terminology is that, in isolation, if we put this product in this room and let it sit on this table, it's not hazardous material. It's hazardous in the context that it may be being used in, so I think that's why it just seems like a very broad statement to call the bumper itself hazardous. It's the fact that the bumper's in the crib that it becomes hazardous. And, I know it's semantics, but it just --

SECRETARY SHARFSTEIN: Let me just say a couple things. The Attorney General's Office has advised us that this is the applicable part of the law to this issue. But second of all, I think, you know, we could have a panel of lawyers kind of discuss this, specifics of lawyers, but that's not the strength of the panel, and I think we'll at a certain point have to be sure if we're interested in pursuing anything that what we're doing fits. I think it's more, we're more interested in your sense of the appropriate level of response to a problem, and I think we're hearing that

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it may be low frequency, but potentially severe, and you know, how, what's the right way to deal with that kind of risk in this context, you know.

I wanted you to have a sense of the legal context but you don't have to make the legal judgment. That will be ultimately, if we go that way, that will be ours.

DR. BEILENSEN: You could probably state that you're declaring this a public health hazard based on the hazardous materials section of the thing. There's ways of doing that.

SECRETARY SHARFSTEIN: Right.

DR. BEILENSEN: There's ways of getting the message out to the public that's not going to explode in your face kind of thing.

Other, okay so we've, wait a second. We've talked about labeling, so the issue is now marketing. Does everyone agree that it should be, using the semantics that seem to be most appropriate for the

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public that should be, that the Department should pursue a public health hazard?

DR. CHENG: So I guess I, I think whatever is decided regarding regulation, I think there has to be education with it, because even if you, as we've already mentioned, even if there's a regulation that says we're not going to sell this anymore or we're not going to market this anymore, they're still going to be out there and if some parents are perceiving that it's protecting their child in some way, they're likely to still use it. So I think education still needs to be done, regardless of if there's regulation.

DR. BEILENSEN: You know what I mean, propose a little devil's advocate thing. There were, I can't remember but when I was in the city, in Baltimore City, we had of the 120, 130 infant deaths a year, when we were doing Kidstat (phonetic) we were studying the issue, there were twenty-something of these either overlays, or things in the bed and they weren't able to

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figure out exactly what.

So as the devil's advocate, why not ban pillows?

We do say the ABC's of safe sleep. We have the education, and this could be added to the ABC's of safe sleep, more sternly, but just to play devil's advocate, why don't we ban crib pillows and crib blankets, and just asking.

DR. WILEY: Why don't we ban crib pillows and crib blankets? I'm asking the same question. No, I think that you raise a good point. I mean, the one thing that I will say about this particular issue is this product, is sold for a very specific use. It's not used anywhere else, that I'm aware of. I mean, I don't know if people put crib bumpers on their clothes lines and let the dog chase them, or, but you put them on a crib.

DR. BEILENSEN: Or you can (indiscernible) maybe when you are carrying them. It's not that, I mean, that's a valid point.

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DR. WILEY: And that's really, that's the only place I've ever seen people use them. And it was designed for that use. It's sold for that use. Actually, you know, it's interesting, I read public comment, too. But it's interesting that people get upset but, you know, you get ripped off because you buy a bed package and it has the sheet for the mattress but it also has a blanket and a pillow and a crib bumper. You don't need any of that stuff, so why pay the extra money for all of that?

So, you know, I think that the one difference here is this is specifically sold for a specific use that we are specifically concerned about.

SECRETARY SHARFSTEIN: And just if I can make one clarification. We did not, in the questions, ask, although you can provide whatever you want but just so we're clear, ask for regulations on use. We asked for regulations on sale, marketing, and labeling. So, you know, we're not contemplating at any point in this a

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use as an approach.

DR. WILEY: So, can I, I asked the panel a question, and I'm doing this from the, I think you probably know where I, my position is on this particular issue. But I think that as we discuss what we want to recommend, I think we need to be aware of what is out there.

There are no states that have done this yet, that I'm aware of. Illinois, I think, is trying but I don't think that they've gotten there yet. The, so that, that means that if Maryland makes a recommendation, or prohibits the sale of the bumpers, we will stand first, and there will be significant public impact of that, positive and negative. Many people will probably look at this and say, we are, it's finally, someone has taken a stand. Someone has finally decided to do what is right. They keep telling us that our babies can die from this but yet they keep selling it. Finally somebody did something more than just say, issued a

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strong warning.

DR. BEILENSEN: And this will, and that will actually get the message out more than any other PR.

It will actually be an educational tool. People will also say it's an anti-state.

Comment [m3]: Should be "a nanny state"

DR. WILEY: Right. We have to be prepared for it. Part of the education process is preparing for the backlash with all of the family members in other states where it's still available and how come their state hasn't, and we have. So either we're smarter than they are, or we're meaner than they are, or we're more restricted than they are, or we're more liberal and, you know, but you can name the label. They'll throw it.

So you have to, I think we have to stop for a second and think about what we're actually recommending for the public. I think it's the right thing to do. I think that Dr. Cheng's point is a really good one. Is there substantial evidence? Probably not. Okay?

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Probably not. But as I've said before, the absence of substantial evidence doesn't imply the absence of cause or the absence of risk. It just means it hasn't been proven in a situation where we can say, absolutely, and statistically, it is a difference between statistical differences and somebody who has more consequences of an ear infection. We're talking about the difference between death, and that's the statistic, that's the number that we're looking at. How many more deaths does this cause because they're there, or if you remove it, how many more lives will be saved? And if it's one, that's enough.

DR. CHENG: I mean, I think the other thing that we should consider is are there any unanticipated consequences if there were banned, and I think that there could be. If parents think that, perceive that it's protecting their kid from banging their head, are they going to have their kid sleep with them and take their kid out of the crib, or stick a blanket in there

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to, you know, make sure that they don't hit their head.

You know, I don't, I don't know what the frequency of that would be, but I'm not sure we can say that there really won't be some harm.

DR. BEILENSEN: That goes right to your point though, significant education would have to go along with this. To do a quick segway to the one other thing we have not talked about per your point, that this, we would be the only, the first place in the country, one other option is to push this to the Consumer Protection Safety Commission, whatever it's called, and make that, make some kind of recommendation to them so we weren't doing it alone. And so, a quick discussion on the Question Number 3, the Consumer Product Safety Commission is in the process of considering the safety of bumper pads. Should the Department provide input to the CPSC on bumper pads, and if so, what should it be?

Dr. Dayal?

DR. DAYAL: I would have to get a better

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understanding of what that would mean, so --

DR. BEILENSEN: They could come out with their own standard. They could come out with almost anything the Department could come out with, on a national level.

DR. DAYAL: But if they don't?

DR. BEILENSEN: Then we've, we've made suggestions in vain.

DR. DAYAL: We could do both.

DR. BEILENSEN: I mean, they, we could move on

--

DR. DAYAL: Right. I guess my position would be that if it's important enough to do, it's important for us to do. If it's not important enough to do, then nobody has to do it. I think that putting it in CPSC's court is sort of, for lack of a better word, passing the buck and hoping that they make the right decision.

I would say, in terms of being first in the state, if it's the right, in the country, that's great.

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Somebody has to do it. I totally agree that there's going to be, I think both of you raise great points around unanticipated consequences. Are people going to manufacture their own bumpers and start sticking them in cribs? Well, that could be its own problem but I think that just supports your other plan on education. But I do think that, I'm not comfortable with CPSC, we can make a recommendation. I'm just not sure that that accomplishes anything. It may, but it may not, and I would be concerned if it does not. Are we sitting here a year from now with a potential death or two or whatever, wondering that we could have done things differently.

DR. CHENG: I think I would, I would make a recommendation to CPSC. I mean, I think that they are the national organization that's supposed to be looking at these kinds of problems, and I think that they need to be looking at this as in depth as they can. I think we probably also need more data, as I mentioned before,

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and they could also be the organization that could help to try to change systems so that we get more data.

DR. BEILENSEN: Would you argue that we should only go to CPSC, or should we also do something here?

DR. CHENG: So I, I mean, I definitely believe in education. I definitely think we should be working with CPSC. When it gets to regulation, I guess I struggle a little bit about it. I think getting to regulation is, you know, is a larger step and I think that you have to have substantial evidence and that you also have to really understand those unanticipated consequences, and I, I'm struggling with that.

DR. BEILENSEN: Okay. I'm your patient, I mean, I'm the parent of your patient, and I have a two month old, and I come to you and I say explicitly, is using crib bumpers in my baby's bed, is there a danger that they may die from it?

DR. CHENG: And I would say I do not recommend any crib bumpers, any blankets, any pillows, because

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there may be a slight risk.

DR. BEILENSEN: Dr. Dayal?

DR. DAYAL: I would say the same thing, that no, I would not recommend it.

DR. BEILENSEN: Why?

DR. DAYAL: Because of the risk of possible suffocation or death.

DR. WILEY: I would say that it poses a risk, and I don't really see a benefit. I'd go into the reasons why I didn't see it was a benefit, and address the issues that they may have.

DR. DAYAL: I mean, I'd ask them why they would want to, I'd start with asking them why they wanted to use crib bumpers and what their perceptions of benefits were, and I would talk about the risk and why that risk is substantial. You know, if you came up with a thousand small benefits, it doesn't add up to balance the risk of what could happen.

DR. BEILENSEN: Okay, so playing devil's

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advocate again, why not just use that as the process to keep people from using the crib bumpers, or would you say that not everyone's going to ask you before they do it?

Let's say I'm someone who's every much opposed to government intervention, and I say, well, why don't you just counsel all of your patients not to use bed crib bumpers because it's a risk of suffocation? Why do we have to regulate this?

DR. WILEY: So, I'll start. I'll put myself out there. So I think that there are two distinctions, and having personal experience in recommending therapy but as life saving can somebody walk away from that therapy to go somewhere else because they didn't like what we recommended because it didn't match with what their family, or whatever their other belief systems were.

This isn't, I don't think that this is necessarily a personal patient provider issue. This is a public

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health issue, and it's the one place actually where I can get my advocate daughter to agree with me, which is that public health is the one place where government has the right and has the responsibility and the, the impetus to do something to protect.

DR. BEILENSEN: Even if there's not a demonstrable, substantive risk, there is a seeming risk but not a demonstrable substantive risk, does the government have a responsibility then to step in?

DR. WILEY: I believe with what we're faced with here, in terms of the information that we've read and what we know, I do agree that that risk is substantial enough, not substantially proven, but substantial enough in that there are proven deaths and medical examiners have written death documents, saying that the crib bumper was responsible, and that's a death. That's not an injury, that's a death. And that's enough.

DR. BEILENSEN: I fully agree. Dr. Cheng?

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DR. CHENG: And I would just reiterate that we need to do education on multiple levels and I would love to see better data on this.

DR. BEILENSEN: All right. So with that discussion, let's go back now through the questions and see if we can answer them to make recommendations.

Under Number 1, Question A, I think we've come up with this so I'll just give it and tell me if you disagree with what I'm saying. Question A, does the evidence support a finding that the use of crib bumpers provides benefits, health benefits to infants? Cosmetic we can't really comment on. I think the consensus is no. There does not seem to be evidence of that.

Number 2, does the evidence support a finding that the use of crib bumper pads proposes a substantial risk to infants? I would propose that the wording be, we have a concensus that there is a risk of death to infants from using crib bumpers, and further research

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should be done on substantial or how much, but there is a risk of death. I think we all agree with that.

Question C, could improved labeling mitigate the dangers associated with the use of bumper pads in infant cribs? I think we came to an agreement that that would not be particularly beneficial.

Question D, should the Department provide input to the CPSC on bumper pads, and if so, what should that input be? I don't know if we came to a concensus, but I would put forth that we recommend that the CPSC move forward with their process of investigating the safety or lack of safety, the dangers of crib bedding, but that crib bumpers, but that doesn't preclude us from making further recommendations of the State.

DR. SMITH: If anyone has a different opinion or would like to make a statement, please feel free. You don't all have to agree, but if you do, that's fine.

DR. CHENG: I guess I would just add to that

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that they consider further data collection regarding bumpers.

DR. WILEY: I would also ask that they maybe look at their data collection tool and try to identify easy to assess, or easier to assess information in cases of infant deaths or infant injuries, severe injuries. It might actually lead to some better outcomes.

DR. BEILENSEN: One thing that was not quite addressed in anywhere in here is since the State Health Department oversees the Medical Examiner, is to have, you guys can make suggestions on what the wording should potentially be, is to have the death scene investigations as you've been mentioning, include that as a check off, because that would deal with the legacies issue.

Question E, is a warning to consumers, this is what the Department can do. Should the Department issue warning to consumers, and is it justified, and if

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so, what do you recommend regarding the content of the warning? I think we agreed that warning just, I don't know what we agreed on. Did we agree on anything on that one?

DR. CHENG: I think, I thought we agreed to education.

DR. SMITH: Just, just for clarification, are you on the Consumer Product Safety Commission?

DR. BEILENSEN: No. No, we're on the Question E. I don't know, what do you all feel? I think that clearly education is crucial.

DR. WILEY: Well, I tend to agree with Dr. Cheng, especially the issue that she brought up before about legacy, because regardless of whether people sell them, they still exist.

DR. BEILENSEN: Yes. Good point.

DR. WILEY: And so I think that there needs to be warning about the use of existing materials that are risky.

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DR. BEILENSEN: Let's come back to that one because it actually, the actual wording of it depends on what we decide to do down the road.

All right. So the final area, and how far we go is should the Department declare this, pursue regulations that define Question F, define crib bumpers as hazardous materials, taking into count Dr. Dayal's semantic issues and couching it for the public in a better term, and for the legal, legal ease for the lawyers. I think we came to the conclusion that that was a yes.

DR. CHENG: I would, I would abstain from that.

DR. BEILENSEN: Do we, do we vote? Do you want to have a vote?

SECRETARY SHARFSTEIN: It's up to you. It doesn't have to be, it could be that each person gives their perspective on the question, and then we can --

DR. CHENG: I mean, we are advisory to you.

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SECRETARY SHARFSTEIN: We don't need, it doesn't, it will, we'll look at everything.

DR. BEILENSEN: Okay. I think we have the three folks, three gentlemen support this. The gentle lady is abstaining, as they say in the Congress.

Question G, if there are regulations to define crib bumpers as hazardous, should they address labeling of bumper pads, and I think we agreed no for the same reasons that we've discussed labeling before.

Question H and I, if the regulations address the marketing, if the regulations are promulgated to push to deem these a hazardous material, should they address the marketing and/or sale? That we have not actually come to a conclusion on. I'll tell you what I actually think, and I think your comments tilted me. This is the, they are explicitly used, they are explicitly sold. This is the only thing that's explicitly sold for use in the crib, and it's completely antithetical to the ABC's of safe sleep, as opposed to the pillows

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and things like that. So I would actually support banning the sale of it. Dr. Cheng?

DR. CHENG: So, that's where I'm struggling as to whether we would ban the sale of that.

DR. BEILENSEN: And let me add one thing. And one of the other reasons for banning the sale, and I would argue for a phase-in period. You know, you tell people a year in advance so that the manufacturers and everything, and that gives us the opportunity to weigh stronger education than to anything else, because there's no mixed message here. The message is very clear. These things are potentially dangerous. There's no benefit. If you have a legacy bedding, get that, get rid of that. These are, this really hammers home the ABC's of safe sleeping in more ways than anything else, I think. But anyway, that's my feeling.

DR. WILEY: Yeah. You know it's interesting. I think what you said, Dr. Cheng, has a far reaching opportunity. If we do education correctly anyway, we

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take away the market for them, and then we actually take away the need for the manufacturers to make them, because they're only going to make them because they can turn a profit. They're not going to make them at a loss, and if we, if we educate people enough that they begin to believe and understand these risks and don't buy them, and just opt out for just the firm mattress and bed sheet, and the crib that doesn't have a slide down, then the other products won't have a market anymore and there won't be a need for them.

DR. BEILENSEN: For the sake of arguing.

DR. WILEY: Well, I'm just saying that your, I think your point is a great one, that giving a year lead in, if we push for very, very strong education and warning in the interim, a year from now there won't be any argument because the manufacturers won't have a market.

DR. DAYAL: I would respectfully disagree with that, because we have lots of public health examples

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where explicit warnings of death, written in black and white on the package over the last 30, 40 years, has not lead to the disappearance of the market, and I also, we have to also acknowledge that not everybody's going to equal access to the education.

So yes, some people will. But there's going to be people who, some people are not even aware of the benefits of vaccines which we struggle with a lot as pediatricians, which is, these are old, 50, 70, 90 year old products that we are still struggling with education on. So I think that while I fully support education --

DR. WILEY: So what you're saying, actually, you've just made your point absolutely crystal clear, if you feel that that is a tried and true defeat in the past history of public health, that the only way to address this situation is to ban the sale? Because anything short that you'll still have a problem. By that argument.

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DR. DAYAL: Yes. And I also do think that regardless of the educational message, there is an implicit endorsement when a product is available in a market, because as people, well, if it's that dangerous, how could you be selling this, is I think, a valid concern from the public.

DR. WILEY: And that statement has been made by the public many other the times.

DR. BEILENSEN: And if we go first as with, there are some examples on the other side, that when you bring, and I don't believe much in the market, the real true free market, because we're not really a free market in this country in many ways. But put that aside. When you talk about trans fat, that has become so big that even things that never had trans fat are saying, "trans fat free." That's the only bad thing.

DR. WILEY: Right.

DR. BEILENSEN: The BPA, another example. Maybe not tremendous amount of evidence for it, but

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everything's now BPA free.

DR. WILEY: Right.

DR. BEILENSEN: So if Maryland does this, it actually could push the CPSC to do this nationally, or use market forces and parents are saying, wait a second. Why did the State ban this? It's not Canada or Australia, it's a state. Okay, so.

DR. DAYAL: But I do agree also with your phase in, because it's not something you want to do overnight. You do want to have opportunities for education, and also I think, too, I think you had made a point earlier that anything, any action around this, this product, will lead to further education around SIDS, safe sleeping habits, and everything in general. Which we will never know what the true benefits from that are, but there's also ancillary benefits of just having a bed.

DR. BEILENSEN: So how do you, how would you come out if you were asked, asked this panel to vote on

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banning the sale of these?

DR. CHENG: I mean, I think if there is regulation banning the sale and the marketing would be the way to do it. I guess I just, I take regulation very seriously. I take the unanticipated consequences very seriously. I wish there was a way to kind of get a sense of kind of public opinion on this, because if the public really does feel strongly that maybe there is some benefit to bumpers, I think there would probably be more unanticipated consequences.

DR. BEILENSEN: You guys see thousands of patients. Again, it's anecdotal, but at the end it's pretty big. How, what's your feel on that? And what, do a lot of parents, do you hear what parents' concerns are? And they're, you know, often first time parents. They're really worried about it. Do they really feel strongly that bedding, and for, a perfect example, the ABC's of safe sleep, okay? The ABC's of safe sleep don't ban things yet. But it's a very clear message

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that most people are getting. How much push back do you get from people saying, well, I love the pillows, and so soft on their head, or do you really, do parents come around when you education them? I guess that's the question.

DR. CHENG: Yeah. I think it's variable. I mean, I think that there's some still that, you know, as much as we talk about co-sleeping as well, that still feel like co-sleeping is maybe safer for their children. So I think, I think that it's, it's variable.

DR. DAYAL: I think that, I agree, it's variable. Most patients, or a large number of patients do rely on their physicians and their pediatrician when it comes to their children as to providing recommendations, and many do adhere to what we say. So I think that if we are telling people that these are unsafe, or that we don't recommend them, then I think it's very consistent with any, with a position around

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saying that we don't think they should be sold.

DR. BEILENSEN: So again, giving a year phase in so there'd be plenty of time up front, does that give the time to do the education necessary to avoid the unanticipated consequences that you, that you clearly, appropriately highlight?

DR. DAYAL: I would think so, because the age group of these children is, you know, six months. So a year, they're, luckily these moms aren't even pregnant yet with these babies who are looking to address this concern. So it's plenty of time between their pre-natal visits, their immediate first checkups, that's there enough phase in time.

DR. BEILENSEN: And where would other pediatricians stand on this, besides the three of you and myself? I'm not a pediatrician.

DR. WILEY: I think most pediatricians agree in principle with all of the practices of safe sleep, that this is a component of that. It's probably not

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the high priority in everyone's mind, but it probably exists.

DR. BEILENSEN: It's kind of a low hanging fruit to me.

DR. WILEY: Most, right, most pediatricians agree with the AAP recommendations for conditions for safe sleep. I think most pediatricians look to guidance, sometimes from the Health Department and from experts who do this all the time and do public health research to come up with guidelines that they can feel comfortable about and to help parents understand and enforce. You know, most practicing pediatricians don't read the literature as exhaustively as we all wish we could, not that we do, but we try. But I think they're looking for guidance for this sort of thing, and many of them, I think have an innate feeling that it's the right thing to do. They're waiting for a core group to sort of bring, you know, have the leaders bring them to battle.

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DR. BEILENSEN: Okay, so, I'm sorry.

DR. WILEY: I think that was important.

DR. CHENG: I mean, I did talk to a few pediatricians, a few of my colleagues about this, knowing that I was coming here. I think that people agree that there's some risk. I think where I got some difference of opinion is whether regulation is the right way to go, and whether it's more education versus regulation, and whether there really is substantial evidence in which to go towards regulation, and, you know, I think some of the commentors also raised that, including the head of the Maryland AAP.

DR. BEILENSEN: Well, on the flip side you could say well the ABC's of safe sleep are going to have to be adjusted, because I think a lot of parents don't see the crib bumpers as part of the ABC, right? They think that's part of the crib.

DR. WILEY: I think that's correct. I think that's a good distinction and an important distinction.

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That they don't look at it that way.

DR. CHENG: And I think some of the colleagues who were concerned about, you know, whether regulation was the right way was just the question about whether it's really hazardous and do we want to be coming out saying bumpers are a hazardous material?

DR. BEILENSEN: That I have less of a problem with. I think there's evidence that there are some deaths. How many, we don't know that are related. And the thing that, overall thing I know we've all sort of said in one way or another is to me, is there are, this is, as Dr. Wiley pointed out, which I actually thought about before, this is specifically for use in a bed. There is some risk, whether substantial or not. There are, there have been deaths due to this. There is no real known benefit, healthwise or otherwise, for using these things. So to prevent even a, I mean, one infant death is a tragedy, and even a public health tragedy, not just the individual tragedy, but there seem to be

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significantly more than that, and why, why even put any kid at risk for that?

DR. WILEY: You know, a single increase in death is not statistically significant in this background noise in the scheme of all public health. But for the family, it's a hurricane. It's a disaster. It's an absolute tragedy.

DR. BEILENSEN: And we saw that in just two of the comments. All right. So, I don't want to overstate it but I think there's at least a concensus, although not a strong push, but a concensus that the Department go ahead with looking at regulating this as a public health hazard, potentially with an abstention, and if so deeming it, if you can so deem it, that you pursue or look into the banning of the sale with a phase-in period and extensive educational efforts on a wide variety of fronts.

I think we answered all of the questions. Would you agree with that?

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DR. WILEY: Well, one thing that you brought up and we didn't really answer was how, you brought this up, Dr. Cheng, which is how to engage public comment and public reaction.

DR. BEILENSEN: But can you do, when you play these regulations --

DR. WILEY: But it does go to the unanticipated consequences.

DR. BEILENSEN: Right. So when you put out these, these would be regs, correct?

SECRETARY SHARFSTEIN: So there are a few different ways that we could do regulations. Some of which, one of which would be through a proposal with the public comment. Another could be with, as an emergency regulation, potentially. So, you know, it depends. But there are different options.

DR. BEILENSEN: I would argue per these points, which I think are all quite valid. Since this is a year phase-in, or we recommended a phase-in

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period, this clearly wouldn't be an emergency regulation. It would be a regulation with the ability for public comment. That would be my recommendation. I don't know, maybe the group could recommend that too, so that there is the opportunity for public comment, and if you hear, you know, 18,000 families screaming bloody murder, then you might reconsider. But, does that make sense?

SECRETARY SHARFSTEIN: I think that's a good approach.

DR. SMITH: So everyone's in agreement with that approach, just for the record? Just for the record. We just, we can't record heads nodding.

DR. BEILENSEN: Yes. Sorry.

DR. WILEY: Yes.

DR. CHENG: Yes.

DR. DAYAL: Yes.

DR. BEILENSEN: We are in agreement.

DR. SMITH: Thank you.

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DR. DAYAL: Can I ask a practical question about the, around the sale, though? What about internet sales?

SECRETARY SHARFSTEIN: I don't know if I can answer that one. I'll have to, if we look at this, you know --

DR. BEILENSEN: I think, you know, a lot of people would like that.

DR. CHENG: I mean, that's why think it needs to go to CPSC, if they're concerned.

DR. DAYAL: Right, right, and I'm sorry, just for clarification. My point around CPSC was saying in isolation, of course, if we should forward our recommendation to CPSC saying let's just not, not just do that.

SECRETARY SHARFSTEIN: And could I ask a follow-up question? Setting aside the issue of the regulation, the warnings/education, could you be a little bit more specific about what you would recommend

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as the content or approach for that?

DR. CHENG: I mean, I would go with, I mean, the Academy has not come out and said ban bumper pads. Some of it's material it is, in the educational material it has. In the statement, I think, which gets revised regularly, they haven't come out and banned bumper pads. But I think that it's, you know, there's no reason for bumper pads, and there's no reason for pillows and anything else in the crib, would be, would be the message that I want to get across.

DR. DAYAL: I think we should also convey our decision to the Academy. Make them question why their position is, for lack of better word, sort of on the fence. I mean, some of the statements are very strong, but they're not direct. They're not saying ban them, but they're also saying that they are dangerous, so that may help move, because that would help a lot of the other, other states taking a stand.

SECRETARY SHARFSTEIN: But what about, I'm

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also asking not just so much, that's helpful and you should continue there. But just one of the points being made is that you, one of the reasons that I'm hearing for a period of education and warning is to avoid the adverse consequences. So, you know, how, you know, is there any recommendations you have on education, perhaps how this message would be tied into the overall safe sleep message, or anything about, you know, if you're recommending setting aside the issue of regulation, this kind of intense educational effort, what are the other components besides saying there's no reason or however you would phrase that one.

DR. BEILENSEN: I think it gives to fully flush out the ABC's of safe sleep that the warnings, that concerns are you mind closely, and so we're actually, we have 3 deaths out of the 14 deaths in Howard County this year are all overlays, from non-inebriated, they're just overlays from co-sleeping. So this gives a, the ability to give that message of the

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ABC's of sleep very strongly in that for those who are, who think that, a couple things. One, you want to include information on the lack of benefits of crib bumpers, and this is not helping to prevent injury to your child, and if you are so inclined to swaddle the baby because you think it doesn't have a comfortable crib thing, no, the ABC's of safe sleep deem that not a smart thing. I would have those kind of, two messages, and then the legacy thing, too.

DR. DAYAL: I think to, specifically to your question, is as part of the communication, whatever, it should be coming from your office or from you about why this is being done, and in the interim what distress, I think the education to be provider focused is what I am saying. I think it's too, perhaps broad, to go to parents at this point. I wouldn't even know, personally I don't know what the channel would be. But I think the pediatrician, family practice, nurse practice community could, would very quickly understand

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what we're getting at and what the concerns are, and with the understanding that in the near future, whatever that date is, that there will not be the availability of these products, what interim steps should be taken around legacy products, around and what the concerns are. I think maybe a summary of actually not this whole packet but maybe a letter, a one page letter saying here's the concerns and here's what we recommend from an educational perspective and here's what we're doing from the legislative perspective would help get that message through.

DR. BEILENSEN: I wouldn't, about the parents. I'm not sure what the best message venue, to get the message to them is clearly through their providers. But there may be, clearly you could do public announcements, too. That's not very longitudinal, there's got to be another way. But I would go for both.

DR. CHENG: Or nurseries, on discharge.

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DR. DAYAL: Nurseries, right.

DR. WILEY: You know, I'm a little ambivalent about that. I don't think it would be wrong to come out with a statement about what safe, what is, what is safe sleep, you know, for babies. We're talking about a crib with a firm mattress, a sheet, without pillows, blankets, without crib bumpers, all of which have been associated with suffocation risk. I mean, that's a pretty simple, straight-forward message that parents would get, I think, and if you did that with a picture of a baby sleeping comfortably on their back, safe, comfortable, effective.

You know, the whole image of, I like the article that you contain there. It isn't for what we're discussing today but the whole issue of, you know, children's magazines, parent magazines that show babies in situations that are really not recommended, too. I mean, couch the message with the picture of the baby sleeping comfortably on their back, in an appropriate

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bed where, on a single sheet on a firm mattress without the bumpers. It would be a nice, effective message, I think. Maybe I'm wrong.

SECRETARY SHARFSTEIN: All right.

DR. SMITH: Okay. I want to thank you for your careful consideration of the comments and the information that was provided. Your recommendations are, will be reviewed and are appreciated. So, I don't know if you have anything else that you wanted to say.

SECRETARY SHARFSTEIN: No, I wanted to just thank you for your time and your obvious thought, deliberation today. I appreciate it and we will let you know as we go back, we'll get a transcript, have a chance to look at that, and we'll take it from there.

DR, DAYAL: I'm sorry. Just to get more clarity on that. What, Dr. Sharfstein, what will be the next steps that we will do and what involvement will we have if any, should we expect?

SECRETARY SHARFSTEIN: We'll probably, you

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know, we'll have a transcript made. We may, you know, give you a chance to make sure that your comments are accurate in the transcript, and then we'll post that to the website so people can see it, and then we'll have a chance at that point to review it in the context of all the information that you've seen and discussed, and you know, I think probably within a reasonable period of time. After that, we will, you know, get a sense of how we're handling it. I have a keen sense of how long regulatory processes can take, I'll just say that. So this will be a lot shorter than some of those. So, you know, we'll basically, in order of in terms of making decisions on how to proceed, I think, you know, by bringing you here it's because I'm interested in understanding this issue and kind of getting a sense of it, and I hope, you know, probably within a few weeks of really having the transcript and being comfortable with it that we could have a basic plan on how to proceed and I'll keep you posted. You know, proceed or

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not proceed, based on what we decide.

Thank you very much.

DR. SMITH: Thank you, and with that, this meeting is adjourned.

(Whereupon, at 4:30 p.m. the meeting was concluded.)

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