BUSINESS MEETING
COALITION OF PET DRUG MANUFACTURERS
VANCOUVER CONVENTION CENTER
WEST BUILDING ROOM 306
JUNE 13, 2022

Steve Mattmuller:

[Slide 1] Good morning, everyone. Welcome to Vancouver. We're delighted to have you here for the Coalition business meeting. Of course, the past couple of years, we've had a couple hiccups with COVID and all, but it's great to see everyone here. I'm Steve Mattmuller, on the Board here with the Coalition. I'm at Kettering Health in Kettering, Ohio. And if I can get this to work, it was working.

[Slide 2] There we go. So in essence, this is our fine print, our disclosure of what we're not going to discuss. Just a reminder that the Coalition is focused on manufacturing issues and not marketing issues. So manufacturing, yes. Marketing, not going to be discussed here today. And as a reminder, all the slides that you see today will be on our website. So if you really are interested in reading all of those, you can see them later.

[Slide 3] This is our agenda for the morning. Following this, my introduction, we'll have the Coalition history and creation of a new trade association, followed by mission, goals, and latest developments, highlights, proceedings from our workshop that seems like it was 10 years ago, but it was only two years ago. The workshop on inspections, management and regulatory considerations, followed by where we hope to go forward. And then with a little bit of luck, we'll have time for questions and answers.

[Slide 4] Here's our team. Most of these people, I'm sure you know very, very well. We have two co-chairs, Sally Schwarz, from Washington University in St. Louis, and our other co-chair is Henry VanBrocklin, from the University of California in San Francisco. Another director is Sue Bunning. Most of you probably remember her as Director of Government Affairs for SNMMI, and now she's the industry director for the trade group MITA. Of course, Steve Zigler from PETNET Solutions, Chris Ignace from Cardinal Health, who unfortunately can't be here physically with us, but he is online. And then Peter Scott, and for those of you who follow Big 10 football, he's from that school up north, otherwise known as the University of Michigan. And then also, we have a number of people online, including FDA staff. So we welcome everyone online. We're glad to have you with us. And with that, I'll turn the podium over to Sally.
Sally Schwarz:

[Slide 5] Good morning.

[Slide 6] I’m here kind of to refresh your minds about what the Coalition has been doing for the last 10 years. We actually began as a grassroots organization, entitled Coalition for PET Drug Approval, and that started in November of 2010. And it was actually formed at the behest of Jane Axelrad. She was then the associate commissioner at FDA. After an SNMMI meeting, a number of SNMMI members, including Henry and myself, went to talk with her, and her guidance to us at the time was that we should form a Coalition of members’ organizations so that the FDA could interact with the Coalition. The Coalition goals in 2010 were to assist PET drug manufacturers in navigating the ANDA application and approval process, also to provide education resources for academic and commercial PET drug manufacturers to achieve this goal.

[Slide 7] We actually held the very first FDA workshop in 2011. Maybe you all can remember we met in a hotel before the meeting, and then we went forward the following day with our questions organized. And we met at FDA workshop held at their headquarters and presented our issues to the FDA. We have developed an informational blog website, which has been hosted by SNMMI. The Coalition initially planned to sunset after the submission of all these potential ANDAs was completed. But, starting in 2012, we kind of shifted focus. We stayed as that Coalition and we shifted our focus from ANDA submissions to FDA inspections, where we still exist today.

[Slide 8] The Coalition was organized and commented on numerous FDA regulations, revisions and guidance documents. It organized and sponsored CE sessions at SNMMI annual meeting and mid-winter meetings. We looked at FDA regulatory and inspection issues, USP monographs and general chapters, and radiopharmaceutical manufacturing science topics. We also regularly held an informational kind of business meeting at the SNMMI annual meeting.

[Slide 9] We recommended the removal of USP monographs for non-approved PET drug products. And we essentially wrote a paper, the “Future of USP Monographs for PET Drugs” and that was published in JNM in 2013. There were recommendations...

Charles Metzger:

We’re having problems with audio being heard by the Zoom attendees. And so we’re fixing that.

Sally Schwarz:

Oh, okay. So may I now proceed? Yes. Okay.

[Slide 9 continued] So there were recommendations made to USP on general chapters. We were involved with the revision of USP <823>, to reflect the organization of the 21 CFR part 212. There was modernization of general chapters <821>, which is for radioactivity, and development of the general chapter <825> on compounding of radiopharmaceuticals. We also had contributions to the SNMMI Quality Systems Personnel Training Program. This is a program that I had developed as my presidential project, and those lectures, which were written by radiopharmacists and radiochemists, again were reviewed by the Coalition, and again, added comments to the various lectures.

[Slide 10] We also now are in the process of creating, and actually have created, a new trade association. In 2021, we began the formation of the Coalition as a 501(c)(6) trade association for PET drug manufacturers. We incorporated the Coalition of PET Drug Manufacturers on December of 2021. We formalized a Board of directors. We hired an executive director, Charles Metzger, who is with us today. We defined membership levels and completed membership solicitation. Recently we have completed the 501(c)(6) filing. We developed a new, more informative website, and the URL is listed here
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(www.petdrugmanufacturers.org). So if you get the slides later, you'll have access to that website. We developed, are in process, actually, of filing a not for profit status, and we are working to complete our bylaws. So we still have a lot of things in process.

[Slide 11] This is the actual Coalition website face. And again, URL is on the first slide and on the last slide so that you will know how to access it. But again, what we're trying to do is provide information for members and help you keep current by just accessing the website.

[Slide 12] So I will step back now with the close of the history, and Henry VanBrocklin will come forward to talk about mission goals and our latest developments.

Steve Mattmuller:

Sorry for a brief interruption. I failed and forgot to introduce our latest and greatest new member of the Board, Charles Metzger. Charles, some of you may know, he is the executive director for the Society of Nuclear Medicine and Molecular Imaging, Southwestern chapter, and also executive director of the society of radiopharmaceutical sciences. So he brings a wealth of knowledge and experience to our group, and he's become our taskmaster. He keeps us focused. He keeps our agendas going. He takes minutes, and he reminds us of the minutes. But he's been critical for us to get to this point. So thank you. Thank you, and welcome to Charles.

Henry VanBrocklin:

[Slide 12 continued] Thank you, Steve, or Matt. Since we have two Steves, we call him Matt. I'm going to briefly talk to you about the missions and goals of the Coalition, and tell you what we've done for you lately.

[Slide 13] The Coalition today represents the interests of more than 150 manufacturers. These are combined academic and commercial PET sites. The Coalition will provide an interface between the FDA and the PET manufacturing community, as we have since our inception. And that's really what we're here for, is to provide this valuable interaction with the FDA, to enable the development of rational and sound regulations and practices. We know we're always being looked at by the FDA, and we have to work with them at our sites. And we're going to work with you to work with them.

So PET drugs demand specific considerations, as we all know, to remain safe and cost effective for use in the clinic. The Coalition is the only organization that is dedicated to these interests of this unique drug manufacturing environment. And we're really stating, we're reinforcing that we're here just for drug manufacturing, not new drug development, not new tracer development. We're just here for the manufacturing. To date, we have received 21 membership applications, and we really appreciate that. And if you have not joined and are interested in joining, please talk to Charles and he will make sure that you get the information. We know there was some issues with getting some emails out to everybody, and we'll follow up after this meeting.

[Slide 14] So our mission is to advance the scientific and regulatory principles associated with the manufacturing of safe and effective PET drugs.

[Slide 15] And we have a number of different goals that we are going to go after to achieve this. Establish the sound and rational practices for PET drug manufacturing, provide multi-stakeholder forum to address current topics with the FDA and other government agencies, through education and information sharing, align the interests of the academic and commercial PET drug manufacturers, provide resources to assist the drug manufacturers with GMP compliance and inspection challenges, and enable the expansion of
new PET drugs into routine manufacturing networks. We’re all facing a number of different challenges. And hopefully the Coalition can help with some of these.

[Slide 16] PET drug manufacturing has evolved. The Coalition has, over the last 10 or 11 years, evolved in this response, as Sally pointed out earlier in our history, what we’ve done in the past and what we’re doing now. The power of the Coalition is, it really lies in you, the members. We really need the membership to engage in the organization to make this something that will be good for every single person. So through the workshops, publications and other activities, we’re going to bring together the PET drug manufacturers and the regulatory agencies to exchange technical knowledge, regulatory standards and best practices. And so this is where we’re going to call on you to interface with us and become a major part of the Coalition. You are the Coalition. In the end, the Coalition advances public health by ensuring the availability and safe and effective drugs.

[Slide 17] So how is the Coalition going to work? So this Board of directors that you see here, and Chris, who wasn’t able to be here in person, is largely an administrative body that’s going to orchestrate how the organization works. So we’re here just to make sure that the lights are on, that we have heat or air conditioning depending on where we are in the country, and keep things running. And that’s what the Board... We’re not here to drive the initiatives. We’re here to facilitate the initiatives of the Coalition, but not necessarily drive it in one direction or another. The Coalition members are actually going to drive the policy, and consensus is going to be what we try to achieve, because you realize that we are working with academic and commercial manufacturers who might each have sort of different ideas of how things need to, or should, get done. And so we are going to work towards a consensus to make sure that it’s inclusive for everybody, that we aren’t leaving anybody out of the process. And so PET operations focus, as I’ve already mentioned, and we want to make sure that we have transparent and consistent communication.

[Slide 18] So over the last few years, the Board has been working to put together, as Sally mentioned, to build this Coalition, to finally give it the nonprofit status and put together this group, make it official. But before that, in February of 2020 as was already mentioned, we held the workshop and we published the proceedings in JNM. And Steve is going to talk about this a little bit more in a little more depth in a few minutes.

[Slide 19] Last week, we submitted comments on the FDA record keeping burden for PET drug manufacturers. This sort of came at us at the last minute, and thanks to Steve and several others, Sue, who was working with MITA to put in a response that helped us to formulate a response on your behalf. This letter and this response will be available on the website for you to look. But we noted that the FDA’s estimate of record keeping burden was at least a factor of 10, maybe even more, low in terms of the amount of time it takes us to do some of the activities. We also questioned, in the response, the FDA’s usage of the term “high risk” without a publicly available risk assessment. So this was part of their language that was in the federal register.

Now we did offer in the letter to work with the FDA to compile a more accurate assessment, an estimate of the record keeping burden and define the risk associated with PET drugs. And this is where we can be of utility in our interaction with the FDA, because we’re the boots on the ground. We’re doing this every single day.

[Slide 20] So with that, I’m going to turn it over to Steve. And he’s going to talk to you about the proceedings from our February 2022 meeting, the last in person meeting.

Steve Zigler:

[Slide 20 continued] Yeah. Thanks, Henry. And I’ll add my welcome to everyone. Thanks for coming out here. Thanks for walking all the way to almost Portland, Oregon, to get here, but at least the view that I
have is really nice out the back window. So thanks for joining us. I think everyone remembers probably the most important thing that the Coalition has done is organized the workshop that was sponsored by the FDA and SNMMI and MITA back in February. It seems like it was a decade ago, but it was really only... it was the last official thing I did before the pandemic hit. So we thought it was important for us to remind the world of what happened at that workshop. And we thought the best way to do that was to write a proceedings paper.

[Slide 21] And so I want to talk about the details of that, but I also wanted just to remind everyone of the workshop itself, since if you’re like me, I forgot about what it was when I started worrying more about this, an N95 mask worked better than a surgical mask. The workshop was held on February the 21st on the FDA campus. Like I mentioned, it was organized by the Coalition and the FDA. It was importantly, very importantly, sponsored by SNMMI, MITA, WMIS, and the FDA itself. It was attended by a lot of people in the audience here, pharmacists, radiopharmaceutical scientists, regulatory affairs professionals, a variety of backgrounds. Importantly, since it was on the FDA campus, we had a large representation of FDA staff members as well. So we had a great exchange of information. The attendees, you know this probably as well or better than I do, represented academic institutions, hospitals, commercial suppliers, and importantly, innovators developing new drugs. Oh, sorry.

[Slide 22] So there were four sessions in the workshop. We had speakers from the FDA, as well as speakers from academic and commercial PET manufacturers. Each session was co-moderated by someone from the FDA and someone from the PET community. We had panel discussions. We had topics that we put together for the panel to discuss at the end of each session, Q and A sessions, we had a live video broadcast. We had questions from the audience, and importantly, there are complete recordings of this available still on the FDA website. So if you’d like to recall back what happened, it’s there. I’ll show you the link to how to get there at the end of my talk. There were about 150 people who attended the meeting, and we had four sessions.

[Slide 23] These are the topics for each session. We had Considerations and Trends and Inspections and Compliance, Lifecycle Management of PET Drug Applications, Chemistry and Product Quality Assurance. And then also looking forward, what’s the Changing Landscape of PET Drugs and Labeling Requirements. And also, importantly, about electronic filing requirements.

[Slide 24] Some of the key discussion points that came out of the meeting were FDA experiences with preapproval and surveillance inspections, trends and observations on inspections from the PET community perspective. So we had presenters offer their perspective from both sides. There was a session where we talked a lot about training of FDA inspectors and a development of a tablet based approach of FDA inspections. There was a lot of interest in this topic from the audience, and also experiences around the lifecycle management of drugs and microbiological considerations. This was also a major topic for the meeting.

[Slide 25] Some of the outcomes from the meeting were that the FDA noted that the PET GMP regulations, that’s 21 CFR part 212, are currently under revision. There was no timeline or anything like that projected for when that might appear. I’ve heard a lot of buzz in the community since then, but that was something that they had mentioned at that meeting. So right now, as far as we know, we don’t know any information beyond that at this point. We talked a lot about the non-uniformity of inspections, and how that creates confusion in the PET community concerning which regulations to follow or what guidance is applicable. I’ll talk a little bit more about that at the end when I get to the proceedings paper. We also talked about the fact that the risk profile based on the inherent characteristics of PET radionuclides and PET drug manufacturing currently does not exist today.
Probably about a year ago, maybe it was longer than a year ago, we started working on authoring a paper that our goal was to submit it to JNM. So at the end of 2021, we polished it off and we submitted it to the journal. It was accepted. It was published electronically, some of you may have seen it already, in January of 2022. We shared it with the FDA as part of an invitation to have another workshop coming up in 2023. Peter will talk about that a little bit more at the end. And that PDF of what we wrote and prepared is currently available for download at the JNM website, and it's free to SNMMI members. Peter's been driving this. We recently completed galley proofs for the paper, so it will appear soon in print, probably in the next journal and in the next issue, or the one after that. So keep an eye out for that. And this is what it looks like on the right hand side here.

So some of the themes that we describe in that paper are here. The need for uniformity of FDA inspections of PET facilities, you've heard me mention that a couple of times, and Henry mentioned it also. This is really important, I think, because we all feel like the non-uniformity of inspections actually threatens the uniformity of the drug supply in the United States. If one site is asked to do something slightly different than another site, and we have 150 sites, how do we correlate that change across 150 sites? And I don't know about you, but I work for a company that manages a lot of PET sites, and change management, change control, is a big deal to us. So imagine what it's like across 150 sites that all have different entities in charge of them. So the uniformity of PET inspections is a really important issue for us.

Also about the same importance, I would argue, is the need for a science based risk profile for PET drugs. Henry mentioned this as well, the fact that “high risk” was used to describe certain types of suppliers of components in the solicitation for comments on the record keeping burden. It's important that we classify things according to a true risk assessment for why something is either a high risk or a low risk or whatever. If you say something is high risk to 10 people, you're going to get 10 different interpretations of what high risk is. We have to have some scientific basis, some standard by which we can measure risk in PET drugs. So we really need to work on this. Also improvements to the training for FDA investigators and the regulated community, both sides. We all need to stay current in this. Things do evolve as time goes on, and we really need to stay current. And then a need for continued dialogue.

You know, I think one thing the pandemic has taught us is the importance of face to face interactions. And the workshop that we had in February at the FDA headquarters was an extremely valuable exercise for everyone, I think, and doing this through email and FaceTime and all that kind of stuff, it's not as good as face to face interactions. So we need to get back to that.

So I mentioned a couple times that these recordings and the proceedings are available. Here are links. I know there's no way you'll get that link. So if you simply Google “proceedings PET drug workshop,” you'll get it. That's how I get to it all the time. I don't have a link on my computer, but I just Google proceedings PET drug workshop, and you'll get to our paper that was submitted to JNM.

Also, if you want to get to the recording that the FDA made and has posted on their website, just Google, “FDA PET drugs workshop,” and you'll get to the recording. It was an all-day session. Make yourself some coffee, maybe a cocktail later on in the day, and enjoy it. I've gone through it in great detail, and so I would encourage you to do the same thing. But that was the point of the proceedings paper too, that we've submitted, is to try to summarize that as best we can so you don't have to sit through eight hours of recordings.

And with that, I would like to turn it over to Peter Scott, who's going to talk about the future. We've talked enough about the past now. I think let's talk about what we're going to do, okay? Peter, take it away.
Peter Scott:

[Slide 29 continued] Thank you, Steve. So you heard a bit about all past and our history from Sally. Henry and Steve have talked about what we've been doing recently. So to finish up here, we want to chat a bit about what the next steps are.

[Slide 30] So you heard the importance of face-to-face communication with the community and the agency. And so, as we cast our eyes to spring of next year, it'll be three years since the last workshop. So we believe it's time to propose a new one, and have done so. So we had contacted Lou Marzella proposing a new FDA workshop, similar in format to the last one, on inspections and other regulatory considerations for our community. The proposal has been acknowledged by FDA, but at this point has not yet been accepted. We of course anticipate that this will be a collaborative effort with SNMMI, MITA, and the other societies that were involved in the last one, as we want this to be a community effort going forward.

[Slide 31] We are putting a request out to you all for volunteers, for a working group to assess effective communication with the Coalition. So you've heard about how we've incorporated as a trade association. Input from members is critical to the success of this initiative. So we would like this working group to consider informational needs of Coalition members. We would welcome input on the most effective forms of communication. We all deal, I think, with information overload these days. So we don't want to be just another email that you ignore in your inbox. So we could use feedback on whether you want more emails, social media, whether we should be communicating through the website. Perhaps we need to create a members only forum. So we would welcome feedback on what you think would be the most effective and useful for you all. If you have thoughts and input on this, please contact Charles. There's email addresses on the slide, and you'll get copies of the slides after this meeting.

We will have a Zoom business meeting that's tentatively planned for the fall, and we'll get the information out on that to you once it's scheduled. And until that time, we'll communicate important Coalition news and activities through email and on the new website.

[Slide 32] So, next steps for us. As was mentioned earlier, we have a few things still in progress, so we need to finalize the bylaws. We are going to create avenues of communication that ensure organizational transparency. So you heard Henry mention this, transparency is an important part of the Coalition, and it's something that we're really striving for here. I just mentioned that we want to organize another FDA workshop. So the hope is that will happen in spring of next year. I mentioned that we've contacted Lou already. Similarly, we would like your input on this. So if there are topics that you would like us to cover at the workshop again, please let us know, contacting Charles.

We want to create this members only community. So again, if you have thoughts on the format and what that might look like, please do let us know. And as has been stated a number of times today, you are the Coalition. We're just here to keep the lights on, make sure the administrative stuff's happening behind the scenes. So if you have ideas and suggestions, we want to hear from you, so please do reach out.

[Slide 32] So with that, we can open it up for a Q and A session. So thank you. [Off microphone discussion] Yeah, we are recording this for the folks online. So we'll make that recording available too.

Q and A

Roy Brown:

Morning, Roy Brown from Curium. Comment and a question. I think it's a great idea to form the Coalition. I think that's a very effective way to get the industry together, and to communicate with FDA. Second
question, is this revolving mostly around part 212 issues? Are there 211 issues you're going to deal with as well? And what might be a benefit to PET producers that produce under part 211?

**Steve Zigler:**

Yeah. Roy, that's a great question. Thank you. 212 defines the Coalition, 211 doesn't. So we're focusing right now on diagnostic drugs, PET drugs, produced under 212. There were no immediate plans, I don't see us going into the 211 world for a while. That's already dealt with in other places. So any other thought? What's the community think of that? Let me turn it around. And I see some heads nodding up and down. Okay. Yeah. I think one thing that we can do that would be a huge mistake would be to just chase after every shiny little thing out there. Right? We got to focus on one thing, 212, get it, do it well. And so that would be the answer to that.

One comment I would like to add that might bring up some questions or even just comments from you all, Peter mentioned that we're soliciting volunteers for helping us to communicate. I'm familiar with a lot of online forums. And so you can make private communities where the members can exchange information privately with each other and share experiences, and things like that. So we are exploring a possibility like that.

I've had a couple of conversations with some people in the audience during the meeting, I'm looking at you, Mariana, about some ideas that we might have for collecting information.

One of the things that the Coalition did before the FDA workshop in 2000... What year was that? 2020? 1992? We solicited feedback from PET manufacturers on a variety of topics. So we have to get good at collecting information. It's one thing to communicate, but we have to have something to communicate, right? So we have to collect information. We have to synthesize this into some actionable items that we can then do something with. So we need to figure out good ways to collect communication from the PET community. And we're hoping that when we solicit surveys or whatever from everyone, please, please get engaged. If there's a better way to do that, let us know, because we don't want to be guessing. We want to be dealing with real information. We want to be a science driven Coalition. So if there's any way to improve that, let us know. Any questions from anybody else? Mark?

**Mark Soffing:**

Just a quick question.

**Steve Zigler:**

I'll repeat the question back.

**Mark Soffing:**

I'll project. Basically when we have this meeting every year, the FDA generally presents. Is there a plan to have a presentation from them during this meeting?

**Steve Zigler:**

Yeah. So the question that Mark had, and I'm going to paraphrase it a little bit, so let me know if I got it wrong, was we have this meeting every year, and typically the FDA participates in it, correct? Yeah. Well, I think this year with the pandemic and the international travel, it probably made it a little too complicated, but in the future, the plan would be going forward to interact with them and get them involved as much as possible. I don't know if you have any chat, if anyone from FDA would like to comment on the chat
about that, Charles, we'll welcome that. But I think this year was sort of an outlier. So maybe next year we'll be back to, quote unquote, whatever normal means these days. Did that help, or did I get it okay, Mark?

*Mark Soffing:*
Yep. Thank you.

*Steve Zigler:*
So we do have some FDA participants that are online right now.

*Reiko Oyama:*
I'm Reiko Oyama from Washington University. First of all, thank you very much for organizing this meeting. I have two questions. One, in 2020's workshop, FDA team mentioned revising the 212. Is there any update of the revision status? If you have any update, it'll be great, if you can share or maybe the FDA from online. My second one-

*Steve Zigler:*
So before you get to your second question, let me make sure we understood it. So you're asking, is there any update on the revisions to part 212? Is that what you're asking?

*Reiko Oyama:*
That is correct.

*Steve Zigler:*
Okay.

*Reiko Oyama:*
Okay. My second one, several weeks ago I just realized FDA is collecting, it's a information collection about 823 and going up to the 212, and then how much work is needed. So is there any idea that work we are doing under 823 will be actually merging into 212 status? I don't want to go kind of off track. So if this is not really a on track issue, it's okay just to go move forward, but I just wanted to ask.

*Steve Zigler:*
Yeah. So, make sure I understand. And you're saying that based on the paperwork burden request that was in the federal register, you're asking how does that information basically feed into or possibly inform revisions to the PET GMPs, right?

*Reiko Oyama:*
Yeah.

*Steve Zigler:*
Okay. So I think we kind of dealt with both of those questions, but I'll go ahead and take those if it's okay with the panel. So as far as the revisions to 212 are concerned, your first question, the Coalition has no
information that isn't available to the public right now. So we are sitting back and waiting just like everybody else to see what will happen. Typically in these scenarios, my understanding is that the FDA will publish a draft of the new regs in the Federal Register, and then there will be a public comment period. So we have reached out in the past, I think even at the workshop, it was brought up that the PET community would be willing to work with the FDA prior to that. I don't know if the rulemaking process allows that to happen or not. It probably doesn't, I'm going to guess, and we'll have to go through the Federal Register process, but we did offer to be involved prior to that if the rulemaking process allows for that to happen.

So the second question had to do with how does the paperwork burden inform the revisions to the regulations? And I don't know the answer to that question either. I don't think anyone does, other than maybe inside in the agency. And I can imagine that they would look at the results from that and possibly revise things as part of their revision process for the GMPs. But I'm just speculating at this point. Just conjecture.

**Reiko Oyama:**
Understand.

**Steve Zigler:**
And if anyone else knows... I don't have a lot of expertise on the paperwork reduction act notice, that rulemaking that the notice was based on. So if anyone has any information on that, I'm more than happy to yield the mic. Okay. Any other questions?

**Steve Dragotakes:**
Good morning.

**Steve Zigler:**
Good morning.

**Steve Dragotakes:**
Steve Dragotakes, Dana Farber Cancer Institute, incoming chair, COR, SNMMI. So at the most recent committee

**Steve Dragotakes:**
Speak up. At the most recent meeting of the Committee on Radiopharmaceuticals, there was a lot of discussion on establishing risk for PET radiopharmaceuticals. And you've addressed that, that you're planning to address that. Do you have a plan in place that you have right now? And let me just follow up. Historically in pharma, industry has, on its own, published scientific data reflecting manufacturing issues. That data and those publications exhibit transparency. So I'm wondering if all of the manufacturers within the PET community are going to be willing for full open transparency when it comes to environmental monitoring and establishing risk, because that data would have to be included in any type of a paper to establish that risk. So that's something we should address, whether people can be open to do that, because the only data we have is all of the manufacturers, and they represent a wide range of workspaces. So I'll let you answer that.
Steve Zigler:
Okay. If I can paraphrase that back. So don't leave that microphone, in case I mess up. So the first part of your question, it really was a comment about how we might go about doing a risk assessment and a need for it.

Steve Dragotakes:
Correct.

Steve Zigler:
I think everyone agrees in the PET community that we need this, and you're absolutely right. We could do this on our own as a community, and this is one of the things we talked about at the COR meeting. And so I think that should be something coming out of the SNMMI meeting here, is we need to start working on it. It would be wonderful if we could do that with the agency in tandem. And we'll see how that plays out.

In terms of the availability of information, especially when it comes to confidential information, you just teed up one of the best reasons I can think of for the Coalition. And that is, you can anonymize data. You can anonymize ideas when it comes through the Coalition, and this is one of the things that trade associations do, right? They do so well, is collecting the information, pooling it, analyzing it, anonymizing it so that it protects the people who supplied that information. And so I think that's a case for why we have the Coalition in the first place. And I think we can do that.

Did that address-

Steve Dragotakes:
That answers, addressed. Good.

Steve Zigler:
Oh, the other thing you mentioned, is there a specific plan? So not yet, not that I know of. There's a huge desire to do that, though, I will tell you that, and we will start working on it soon.

Steve Dragotakes:
So Steve, you just indicated that you would partner with FDA to speak with them, to establish what they think would be a pathway to establishing high risk?

Steve Zigler:
Well, we'll work with them in any way we can.

Steve Dragotakes:
Can I just make one suggestion, that it might behoove us to go out into the greater compounding or manufacturing field to see where possibly academic sites who have expertise in this area would be willing to come in with us to-

Steve Zigler:
Absolutely.
**Steve Dragotakes:**

Work on that. I can't speak to that. I know University of Tennessee has always been strong in sterile compounding, so I'm not sure who is the leader right now, but that might be a good opportunity to partner and gain some sort of justification or defensibility with respect to the FDA.

**Steve Zigler:**

Personally, yeah, you're absolutely right. We need to have someone with expertise in risk assessments in general. Right? So, yeah, absolutely.

**Steve Dragotakes:**

Thank you.

**Steve Zigler:**

Thank you, sir.

**Peter Scott:**

Can I get a quick show of hands? Would people be willing to share data?

**Steve Zigler:**

Okay. Excellent. So the question was, would people be willing to share data? So yeah, absolutely. And that's what we need, man. We need an engaged Coalition membership, and an engaged Coalition membership is going to share data. Right? Everybody, right? Yeah.

**Mike Nichols:**

Mike Nichols, Washington University and incoming president of RPSC. And I know any comments that are made here is preaching to the choir, because we're all here because we're interested. And obviously the RPSC would be willing to help at the SNMMI level, but from a user or a facility standpoint, and I assume... I hope we're members now because I've been pushing for that stupid paperwork to go through, what we don't want to hear as a member is that leadership is working on it. So clear and transparent what the thought process is when you say, oh, we're working with the FDA. We're going to get something done. We want to know what that is, what the thought process is to make sure we're all on board. And it's just a comment.

**Steve Zigler:**

Yeah, no, it's a great comment, too. And we recognize the need for it. We recognize that looking back, there have been times... Well, actually a great example is this paper burden. Did you see what we submitted for the paperwork burden? No, nobody did. Where's the transparency in that, right? Well, we found out about it on Friday and we wrote it over the weekend. So there's a reason for that, but going forward, absolutely. It needs to be an engaged and informed and a very transparent process. It's not a Coalition without transparency.

**Sally Schwarz:**
I want to say, I think one of the things that we're trying to do with this new website, too, is provide an area where there will be information available as to what we are doing, and that you can also ask questions and put in your feedback into what is ongoing. Hopefully this will be a continual process all throughout the year. It's not going to just happen at these meetings or at the workshops. What we're trying to do is work together collectively to be able to achieve these goals. And the only way we can achieve them is with your input. So again, if we figure out a way how you want to communicate with us, we've started the website. We've begun that focus, but as Steve was mentioning, there are other possibilities. Is it a LinkedIn group? Is it a Facebook group? Is it a-

*Steve Zigler:*  
A forum, an online forum?

*Sally Schwarz:*  
Forum? So again, think about ways that really you can talk to us. And then it's not just, you hear what we've done, but you're part of the process.

*Steve Zigler:*  
So Mike, can we sign you up as a volunteer for our communications group?

*Mike Nichols:*  
With an understanding of what I'm doing.

*Steve Zigler:*  
Well, if you feel like you can, please let Charles know. If anyone's interested in just volunteering for anything, there's two or three other things, like I said, that we've thought of here. So if you're interested in, Charles, I want to be a volunteer, send the email to Charles.

*Sally Schwarz:*  
Yes.

*Steve Zigler:*  
Mark?

*Mark Soffing:*  
So with the FDA's interest and input in seeing the formation of the Coalition, would it be... I would propose or suggest that as far as the release of future drafts for comment, that possibly there could be a better interaction between the FDA on those publications. The one that you said about the documentation was released in April, and pretty much it hit everybody the weekend before it was going to be due for final comments. So it might be the best way to look at it as the Coalition being a point of contact for release of drafts that are affecting PET.

*Steve Zigler:*
Yeah. And as a community in general, we need to do a better job of having our ears and eyes open on the federal register for things like that to happen. So we need to do a better job of-

**Mark Soffing:**

Communication in both directions is extremely helpful. It makes life a lot easier.

**Steve Zigler:**

Yeah. Thanks, Mark. Sorry, I didn't mean to take this part over.

**Sally Schwarz:**

That's okay.

**Nick Fryberger:**

Nick Fryberger, BAMF Health. First, I just wanted to thank you guys for organizing this.

**Steve Zigler:**

What was your name again? Sorry, speak up a little bit.

**Nick Fryberger:**

Nick Fryberger, BAMF Health. First I just wanted to thank you guys, and everyone here, for organizing this meeting. I think that the Coalition's missions and objectives really align with what Banff is doing. But my question was, it looked like from the slides that the next business meeting would be probably be fall of this year. Is there opportunities to have, I guess, more, whether it's monthly or something like that, reoccurring meetings, or being able to maybe sit in on a Board meeting just to have more transparency between members and what the direction of the Coalition is going?

**Steve Zigler:**

Well, yes, absolutely. Anything's possible. And I think that one of the things, and I think Peter alluded to this, was information overload, in a way. So what's the right frequency? I think it could very well be more common than twice a year, but what would be a good frequency is a good question. I don't know. Does anyone up here have-

**Sally Schwarz:**

Henry was just talking to me about this, that maybe possibly we could organize once a month where we'd have a Board meeting that would be open Zoom, so that basically you'd have the URL. You could join the Zoom call and that way, you can have your thoughts known, you could talk to us. Yeah, I think that that's a very good idea.

**Nick Fryberger:**

Yeah. Perfect. Thank you. Yeah, whatever... And I don't claim to have the answer for what is best, but working through what works.

**Sally Schwarz:**
And the thing, too, about having questions or answers, sometimes just listening to the discussions that ongo at the meetings, then you understand how we think, even. So just being on the Zoom, you not necessarily have to participate, but you can learn just by listening, how we work through problems. And trust me, that’s what we do.

**Steve Zigler:**
Thank you. Thanks for bringing that up. Anything else? Still got time for a few more questions, but we can also head to the wrap up if you'd like.

**Sally Schwarz:**
Can I say something else?

**Steve Zigler:**
Yes. You can say.

**Sally Schwarz:**
I think one of the things that really you need to focus on, I think, is the next workshop. You need to start really thinking about issues that you have and topics that you’d like to have considered, and start writing things down and send them, or be on a Zoom call and present them, whatever. But I think it's very important, because it takes a significant amount of time to get these meetings organized. You know, we have to decide when we can engage the FDA, when they can have time to do this, and then getting all the pieces together, it's quite an undertaking. So start thinking now about what it is you want to begin to address.

**Steve Zigler:**
[Back to Slide 28] So just a second. So this proceedings paper is a really good read for you to inform what topics you might want to have for the next one. So take a look at that proceedings paper when it comes out. And like I said, it should be coming out very soon, probably the next edition of the JNM. It'll be in JNM Special Contribution.

**Steve Dragotakes:**
Could the Coalition start collating incidents and any documentable observations? Could you start doing that right now?

**Steve Zigler:**
Start collating inspection observations?

**Steve Dragotakes:**
Exactly.

**Steve Zigler:**
Sure. We could, yeah.
Steve Dragotakes:
Are you going to start doing it now?

Steve Zigler:
Absolutely.

Steve Dragotakes:
Good.

Steve Zigler:
This is definitely-

Steve Dragotakes:
And could it be made available, say, on a monthly basis?

Steve Zigler:
Well, I mean, that's probably going to be the most sensitive information that a PET drug manufacturer would share with the outside world, would be their observations on a-

Steve Dragotakes:
So you could do it anonymously, initially, until it hit the paper-

Steve Zigler:
Once we develop the framework in which to do it, that's the thing. We got to develop what's the best way to do it.

Sally Schwarz:
Right. And I think that in inspectional observations are really the point of much discussion. So if we're collating all of these from that, we can also then draw topics for the workshop.

Steve Dragotakes:
Yeah. What I find is that the observational letters are official, however, commonly there's a lot of interplay between the facility and the inspector that could inform us as to thought process. And I think that actually is more important. It's the interplay. If you could anonymously build some comment, because the observational letters are specifically restricted to the code of law. But there's a lot of interactions that I think we could all learn from that never gets published.

Sally Schwarz:
Right. Well, and those have to be written down and then anonymized and submitted. Yes. But I totally agree. It's that background information that helps form-
That'd be great.

*Sally Schwarz:*
Yes.

*Steve Zigler:*
And that online forum could be a great tool to share the anonymized information.

*Steve Dragotakes:*
Excellent. Thank you.

*Steve Zigler:*
Anything else?

*Steve Mattmuller:*
Great. Well thank you all for showing up. We appreciate your interest, your support, but before we do though, I think we need to recognize Sally and Henry and Steve for their dedication and commitment to these topics. Because it's hard to estimate hours, excuse me, days they've put into this. And they're generous because they let me join the group too, because I'm a little guy. But I mean, for the workshop alone, we were meeting once a week for at least a year beforehand. And since the workshop, we've been meeting every Monday. And the best thing about this meeting being on Monday is that Henry's giving us the day off from our afternoon teleconference. So we're really happy about that. But the community owes a great debt of gratitude to these three, because they've been huge.

*Sally Schwarz:*
I'm going to say something. Thank you. Thank you all. But you know what? We don't exist if it's not for you. So just remember that this group is best if it really works together. You need to take the time to get the information down. Don't just do it as an afterthought. Think of working this into your life. I mean, it really is important. We need to interact with the FDA. The FDA wants us to interact with them. We have different points of view, but again, we have to work together. And so the bottom line is, just remember, keep recording what you need from us and get it presented to us and do your part, because we need you as you need us. We're driving this, but you are the members, and you are the important people. Thank you.

*Steve Mattmuller:*
Thank you all.

[Recording stopped]