Transcript for NHPCB Town Hall Meeting

with Industry Focus

September 13, 2023

Ron Whitmont, MD - Moderator

- Tonight's meeting is specifically geared for industry. I'm Ron Whitmont. I'm a former president of the American Institute of Homeopathy. And I currently serve on the Board of Trustees of that organization. I'm chairman of the Board of the NHPCB and chair of the Strategy Committee.

- The NHPCB is a nonprofit organization sponsored by the American Institute of Homeopathy and formed in 2020. Our group is composed of volunteer members from across the entire homeopathy community, including consumers, practitioners, brand owners, and manufacturers. We've been working over the last three years since 2020, but most of us have been concerned about what's going on ever since the FDA held its public meeting back in 2015.

- The FDA's finalized guidance refers to homeopathic medicines as unapproved new drugs, and we believe that the FDA's primarily concerned about potential safety issues. There is concern in the homeopathic community about what we can do. We strongly support the efforts of other groups like the HPCUS and Americans for Homeopathy Choice in their work with Congress and the FDA, but we know that that work takes time. In the meantime, the NHPCB has been meeting on a regular basis to develop standards that we believe are appropriate for homeopathic medicines to ensure proper labeling and production, and we hope to act as an independent third party certifier granting a certified homeopathic seal to manufacturers and brand owners who have successfully completed an application and review process.

- The seal should help consumers identify properly labeled and verified homeopathic products.

- The seal will also help manufacturers and brand owners who are registered with the FDA and who adhere to these standards help them gain recognition for a job well done.

- Since 2017, the FDA has been applying increasing pressure on manufacturers and brand owners.

- The homeopathic community has lost several major producers.
    - Importations have been blocked.
    - Major distributors like Whole Foods are planning to remove some products from their shelves.
    - Lawsuits have been filed and warning letters have been recently sent out to manufacturers of homeopathic ophthalmics, calling them illegally marketed drugs.
    - So, we are beginning to see the effects of the pressure that the FDA is putting on the entire homeopathic industry.

- We at the National Homeopathic Product Certification Board believe that this has happened primarily because the FDA overestimates the risks and underestimates the benefits and consumer demand for homeopathy.

- We hope to help correct these misunderstandings, primarily by providing accurate safety and sales data to regulators through a unique homeopathic adverse events reporting system that will accurately reflect the impressive safety record of homeopathic medicines.

- Our board has asked for and we have received advice from many stakeholders in the community. Our goal is to form an independent, third-party certifying body. This will allow industry to show that it is capable of self-regulation and thereby agree to adhere to a set of common standards.

- Currently, manufacturers that aren't labeling or manufacturing correctly pose a risk for everyone in the community.

- The FDA does not verify or even have the expertise to know whether a product is actually homeopathic or not. Nor do they seem to care. The NHPCB Certified Homeopathic Seal will identify this.

- No one knows what the true rate of incidence of adverse events are to homeopathic medicines. A homeopathic adverse events reporting system will provide meaningful real-world data so that researchers and agencies like the FDA will have more accurate information.

- Brand owners and manufacturers are under incredible pressure today from the FDA. They need a boost in the marketplace, and this seal will help support them. The National Homeopathic Product Certification Board has been working diligently over the past three years, largely because of the incredible faith of our volunteers; their faith is in homeopathy.

- We want to see homeopathy reach its rightful place in healthcare, and this will not be possible in the current environment. Homeopathic medicines need appropriate standards, and manufacturers and brand owners deserve recognition when they do things the right way. Our goal is to support the industry making these medicines so that homeopathy will not be lost from inappropriate manufacturing.

Our speakers/presenters tonight

- Doctor Todd Rowe, who is chairman of the Steering and Standards Committees.
- Betsy Lehrfeld, our attorney, has lent her expertise to our Steering Committee.
- Mike Evans, a brand owner and a contract manufacturer who has worked with our Standards Committee.

Todd Rowe: I am a homeopathic physician and a member of the American Institute of Homeopathy. I have worked as a formulator, researcher, and consultant to the homeopathic industry for the last 25 to 30 years. Over the years I've had considerable experience with certification boards, accreditation boards, and the writing of standards. I've now been working with the NHPCB for several years. I serve as the chair of the Steering Committee and the Standards Committee, and I also serve on the Applications Committee. It has been a labor of love and the process to which I have been deeply committed.

- I would like to say a few words about who we are. The National Homeopathic Product Certification Board is a nonprofit that is sponsored by the American Institute of Homeopathy. We have been working on this endeavor for nearly three years. Although the idea of this goes back at least 10 years, we are a volunteer-based organization and currently have about 30 volunteers working as part of the organization.
- Our mission - the National Homeopathic Product Certification Board is a nonprofit organization providing rigorous homeopathic product verification to preserve and protect access to all homeopathic medicines and to empower people to safely care for themselves and future generations.
- Our vision is to strengthen confidence in homeopathic products through rigorous product oversight and self-regulation by the homeopathic industry.
- We also have a series of core belief statements which you can find on our website. A few of these include that
    - We believe that independent verification of authenticity and safety is designed to promote trust in homeopathic products.
    - We also believe that the certified homeopathic SEAL is designed for the public to increase confidence in homeopathic products.
    - We believe the homeopathic community in the United States would be well served by an updated federal framework that reaffirms the unique nature of homeopathic medicines and appropriately addresses the specific conditions and requirements related to their manufacture, labeling promotion, distribution, and use.
    - We believe such a framework would assist the work of the NHPCB and regulatory authorities in protecting access to the full range of homeopathic medicines while ensuring their safety.
- Our scope for this project includes product certification, brand owner registration, manufacturer registration, and retailer registration. Eligibility requirements for each of these are listed on our website.
- Our primary focus is on product certification. We currently have standards for two pathways for product certification.
    - Pathway #1 is for single ingredients listed in the Homeopathic Pharmacopoeia of the United States.
    - Pathway #2 is for complex formulations with all ingredients listed in the Homeopathic Pharmacopoeia of the United States.

      We plan on adding four additional pathways in the future. These will include pathways for products containing ingredients not listed in the Homeopathic Pharmacopoeia United States, as well as homeopathic products targeted at the treatment of animals.
- Product applications are for homeopathic products only and are submitted by the brand owner.

- All the active ingredients must be homeopathic.
- Product applications are route of administration specific, and we are limiting initial applications to oral and topical preparations only. We plan on expanding this in the future.
- Product applications are not potency specific; so, a single application can be used for multiple potencies. In addition to our review of active ingredients in homeopathic formulas, we also do a review of inactive ingredients as part of the verification process.
- We only review a sampling of the company's product offerings. The number of products that we review for a given company is determined by the number of products that they offer using a risk-based approach, and ultimately these are chosen by the NHPCB.
- Applications are entirely voluntary. Successful applications will allow the brand owner to place a certified homeopathic seal on the company's products.
- Key to this initiative is that we are an independent third-party certification body assisting the homeopathic industry to achieve the benefits of self-regulation. This is not an industry initiative, nor is it a regulatory body initiative.
    - Self-regulation is independent of both industry and regulatory bodies and is a step that many healthcare industries use to approach regulatory challenges and have found to be very beneficial.
    - As we have moved forward in our process, we have reached out to a number of other self-regulatory bodies and have learned from their experience with their industries. Some examples have included
        - Some examples have included The National Animal Supplement Council or NASC.
        - The non-GMO project.
        - United States Pharmacopeia, or USP
        - The National Sanitation Foundation, or NSF.
- The primary focus of the National Homeopathic Product Certification Board is around safety. Although we recognize that homeopathic products have an extensive history of safety in the marketplace, recent actions by the FDA have raised safety concerns regarding certain homeopathic manufacturing practices.
    - Products which are mislabeled as homeopathic.
    - The potential toxicity of certain homeopathic ingredients, if not properly manufactured.
- The NHPCB will help to raise confidence regarding the safety of homeopathic products through verifying that the companies and products meet accepted community standards.
- We are also planning on the creation of a homeopathic adverse event reporting system or HAERS. As part of this initiative the system will be much more robust than the current FAERS system used by the FDA.
    - Similar systems to the HAERS have been successfully used in other sectors of the healthcare industry to help demonstrate relative Product Safety.
    - Not only can this reporting system be potentially useful for regulatory bodies but also to the larger scientific community.
    - As we develop this system more, we hope to have future town hall meetings on this topic.

- The American Institute of Homeopathy was chosen to sponsor the NHPCB endeavor because of its independence from both industry and the regulatory system.
    - AIH is the oldest extant national medical society in the United States.
    - Historically, the HPUS was housed in the AIH before becoming independent in the 1980s.
    - The FDA has also demonstrated great respect for physician-based organizations.

- Where are we today with this endeavor?
    - We currently are in a public commentary period on pathway number one and number 2 standards.
        - We welcome your feedback.
        - We have received many comments today.
        - We have made considerable changes to the standards based on the feedback we have received to date.
    - We are planning to begin accepting applications for pathway #1 and pathway #2 submissions in early 2024. We are hopeful for widespread participation by industry.
    - We have been in communication with the FDA about this organization. We met with the FDA initially, and we just received a letter from the FDA in the last week and are in the process of responding. In their letter, they thanked us for the opportunity to continue to engage with us and said that "we are hopeful about the potential of this approach and that we remain positive about the prospect that robust accredited standards for homeopathic products could be beneficial to both the industry and consumers." The letter also raised some valid concerns about our standards and standards processes which we are addressing, as well as giving the FDA more information on the processes by which the standards were derived. We are also in the process of making changes to the website. Based on comments received from the FDA, the FDA has asked that we pursue formal accreditation for our standard setting process, and we are accelerating our time frame on this and beginning the process of pursuing American National Standards Institute accreditation or ANSI We are also in the process of reaching out to the FDA about the homeopathic adverse event reporting system.

Ron: Would you mention something about application fees and the cost to manufacturers for applying? That's a concern that's on many manufacturers' minds.

Todd: Ron, we are a nonprofit, so our goal is not to make a profit on this endeavor. We have worked very hard at limiting our fees to the minimum amount necessary to continue to run the organization successfully; so, that was how our fee structure was based.

- The other realization that we came to early in the process is that for some of the larger companies, submitting all of their products would be cost prohibitive, and so that's why we have designed a system where companies only need to submit a percentage of their products, and that percentage is based on the number of products that they produce.
- We also are engaging in a fairly sophisticated software system that will help us manage the applications, and we believe that by having the sophisticated system, it will reduce the amount

of time necessary to review applications. We can automate some of the functions that will be necessary, and that will also help us reduce our costs.

- You can find a listing of all our fees on the application section of our website.
- We'd also, if you'd like to reach out to us, be happy to meet with you one-on-one to go over our fee structure and how it would apply to each individual company.

Ron: I'd like to introduce our attorney, Betsy Lehrfeld. Betsy, would you please say a few words about yourself, your qualifications for working with the NHPCB, and then mention why self-regulation is important for the homeopathic community?

Betsy: I'm Betsy Lehrfeld. I'm with the law firm of Swankin and Turner. It's a law firm that's been in Washington, DC for over 50 years. The founders, Jim Turner and Dave Swankin both had extensive experience with regulatory agencies. Jim was the author of the Chemical Feast, the Nader Report on Food Protection at the FDA, and he worked with FDA matters for his long career. I've worked on FDA matters for about the last 40 years. We work with supplement companies, with associations, with practitioner associations, product associations, and individual practitioners and consumer organizations with an interest especially in integrative health and natural products and natural health. I'm a long-time patient of homeopathy. I think it's an extremely important form of healthcare for America.

- For reasons that probably everybody on this call fully understands, since 2015 the FDA has had some sort of change of heart and decided that after 80 years of not having safety problems with homeopathy, this was now something they wanted to focus on.
- They've ended up with a final guidance that applies, basically, allopathic pharmaceutical standards and pre-market approval to homeopathic products which was never used before and which is essentially putting much pressure on industry and they seem intent on enforcing those kinds of standards by increased inspections and sending out untrained inspectors who have no real comprehension of homeopathy and how it works and are exaggerating the safety concerns.
- As far as we know, there's been no serious safety problem from a properly manufactured and authentically homeopathic product. This poses a situation where the homeopathic community really needs to find a way to communicate with FDA and urge them to be using a more appropriate set of standards for an industry and a marketplace that has exhibited an unparalleled level of safety.
- Many other industries and many healthcare practices, that are new, innovative or non-mainstream have used the process of self-regulation and certification to become known. To become respected. To show that they are responsible members of the marketplace. This mind you can do nothing but help homeopathy.
- FDA has already been willing to give the National Homeopathic Product Certification Board leadership a seat at the table and sit down and talk with us. They have exchanged information and we are in the process of providing them additional information that they haven't yet seen in response to their letter expressing some concerns.
- So, I feel that the board and the certification process will have a very salutary effect on the standing of homeopathy in the minds of regulators. I think that its time has come.
- I think this organization definitely has the capability, the independence, the expertise, the commitment and the drive to make that happen.

Ron: Some members of industry have expressed concerns about confidentiality. Can you address briefly how confidentiality will be handled and how can you address those concerns?

Betsy: This has been a major concern from the beginning because the application is going to require some data that may be proprietary. In negotiations with the third-party software provider, which has a lot of expertise in doing very similar processing, we have emphasized the importance of assurance and of being able to demonstrate that assurance of complete confidentiality for any information submitted by manufacturers or brand owners.

Ron: We know there's a lot of different efforts going on in the homeopathic community to reach out to the FDA, and to reach out to Congress. You work both with Americans for Homeopathy Choice and the NHPCB. Can you say anything about the relationship or whether these efforts either complement or oppose each other?

Betsy: I think these efforts are entirely complementary. The goal is to have appropriate regulation of homeopathic products. And that's the goal of, I think, all of the organizations that have anything to do with homeopathy. How to get appropriate regulation in the face of what has become inappropriate regulation. I think that the standards developed by the Board are a way to model the direction of appropriate regulation and to help show that the industry is interested in regulation and wants to be appropriately regulated. I think that's a very important statement to make.

Ron: Thank you very much. I'd like to move on now to Mike Evans. Mike, would you please say a few words about yourself and your involvement with the National Homeopathic Products Certification Board and maybe speak also to the kind of the pressures as a manufacturer and a brand owner that you're under today.

Mike Evans: Good evening, everybody. I know many of the faces. Thank you for coming out tonight. It's a very, very worthy cause that we're all engaged in throughout the industry.

- I have offered my time and experience on the regulatory and quality control side for information based on the fact that I've had the good fortune to sit with the Food and Drug Administration in my facility about six times in the past eight years. So that's a lot of experience in trying to see what it is that they're trying to figure out.
- When it comes to the pressure - the Food and Drug Administration, over the last 80 years, has done little to engage our community in determining what it is that makes us so unique and attempting to integrate that.
- In the 1980s when the compliance policy guide (CPG 400.400) was brought forth that was really a huge undertaking and for it to have dissolved, as it did with no replacement has left our industry under an immensely - I don't know the best word for it, but – a pressured environment to perform to the standards that the allopathic community has had 80 years at the table to work and develop and we have never had that chance.
- The efforts of our entire industry have got to come together for us to pull this off. This effort, right here, for the standard setting and creating these standards that we're hopeful will benefit not only the marketers, the manufacturers and everybody, but it will benefit the Food and Drug Administration as well, because they do not have expertise.

- Please know that when I sit across the table from the FDA, the first three days of the week that they're visiting with me I spend my time helping them understand who we are and what we do. And it's unfortunate because that shows how deficit our industry is in participation with the agency.
- So, my hope beyond all hope is that we, together, as an industry can use the tools of our industry and throughout all of the organizations to bring us to the table as a group.
- Many of you saw the events of yesterday and there are a significant number of players who got warning letters.
- I was taken aback by the method in manner, you know, we've lost the injectables now they're after the eye care products.
- And if anybody paid attention in the 2015 and then following on in the 2017 statements of risk-based management of our industry, they're running right down the list. Unfortunately, they are unchecked at this point. We do not have a seat at that table and we've got to get there and we need to rally everybody throughout the entirety of our industry to get there.

(35:39) Ron: Thank you, Mike, for your call for community involvement. Can you speak at all from your experience - Does this bring anything to the table if we are promoting self-regulation as a third-party certifier? Does this interfere with what you're doing? Does this help what you're doing? Can you speak to that?

Mike: So I think it absolutely brings benefits.

- The Food and Drug Administration has throughout the course of time stated that they don't want to “quote - unquote” regulate industry. They would rather inspect industry.
- So the establishment of a group similar to the American Herbal Products Association, the NASC, and many other groups that are out there today that have traveled this path, and gained recognition have seen it ease the pressure on their industries over the course of time.
- It is time for us to be in that group. Because if we stop, or if we fail, or if we choose not to do so I don't think that the result will be handled very well.

(37:08) Ron: If the FDA is already inspecting companies, what does the seal provide that the FDA has not already provided?

Mike: So, the FDA will continue to inspect. The difference, in my perception, is the communication of our industry.

- Helping FDA know what it is that we do at a level that they (FDA) can develop an understanding. Potentially having people in their midst that understand who we are and what we do.
- Having a set of rules that we can be checked by rather than having this overarching unattainable expectation of our industry.
- The fact that the words illegal and new drug and all of those are bantered about is pretty damning for us. It puts us in a position that allows for some legal challenges for us.

- Those terms, illegal especially, is exactly what the courts of law pursue and I don't feel that we're given a fair shake in that, we've been around a very long time and our track record of safety is just truly incredible as compared to the other medicines.

Ron: Thank you. We hope that there will be widespread support for this seal.

- We hope that your company will choose to support this work.
- There are other ways that you can help and that community members can help.
    - So the first would be to apply for the seal when our enrollment period opens up.
    - The second would be to review the standards on our website. https://certifiedhomeopathic.org/nhpcb-seal-standards/
    - If you do review the standards (several organizations have already reviewed the standards) you can also submit comments on the website. https://certifiedhomeopathic.org/standards-comment-submission/
    - We look at those comments, we have changed the standards already in light of comments. So those are very valuable to us.
    - Another way that people can help is by volunteering to help. We still have a lot of work to do in this certification board and much of it is just getting underway now. But there's a lot to do before we even accept applications. We need people with expertise, and we need assistance. Visit the website to volunteer today. https://certifiedhomeopathic.org/volunteer/
    - You can also subscribe to our newsletter. We urge all of you to subscribe and to stay up to date. https://certified-homeopathic-seal.ck.page/3b28b7eb8d
    - You can donate. We are not an industry supported organization. We have not accepted any industry support other than advice. This has been entirely community supported. If you wish to donate please go to the website and click on help support our work. https://certifiedhomeopathic.org/donate/.
    - Another way you can help is by telling others about the National Homeopathic Product Certifications. Spreading the word on social media or through e-mail is very helpful.
    - And, we can help you. If you are considering applying and you have questions, just contact us by using the 'Contact Us' tab on the website. https://certifiedhomeopathic.org/contact-us/.
    - If you need someone to help walk you through the program, or walk you through the costs, or estimate anything about the amount of manpower it needs, contact us and we will make sure that that happens. We'll make sure that you're hooked up with someone who can help.

Ron: Questions from the attendees:

- (42:40) What kind of comments have already come in on the standards and what has the National Homeopathic Products Certification Board done about those comments? And who has made the comments?
  - **Todd:** I haven't totaled them, but I would say probably on the order of 150 comments to date on the standards and we have reviewed each of those individually and looked at the standards and the comments and we have made extensive changes to the standards based on the comments we have received. I'm not sure that I feel comfortable sharing who has provided comments. That may be confidential. But I can say the types of comments we've received. We've received comments from individuals. We have received comments from organizations. We have received comments from brand owners. We have received comments from manufacturers, and we have received comments from the FDA. So, it's been a broad spectrum that we have received today. Then we reviewed all those in detail.

- (44:20) How does the seal differ from what you see on a label now where it might say a product ingredient and then it might say HPUS? How is the seal going to add quality to that?
  - **Todd:** Adding HPUS to the label is critical. It is indicating that something is manufactured according to HPUS standards. However, currently there are a limited number of medicines, homeopathic ingredients, that are listed in the Homeopathic Pharmacopoeia of the United States. Roughly 1200 to 1400 ingredients are in the marketplace. Homeopaths use 8000 different ingredients. So, there are many ingredients that are not listed in the Homeopathic Pharmacopoeia of the United States that are used in homeopathy on a regular basis. Our vision is broader and larger than just those ingredients that are listed in the HPUS. One of the things that we (NHPCB) do with pathway #1 and pathway #2 is that we require those ingredients to be listed in HPUS. And as part of the label that they use the words HPUS as appropriate. So we'll be reviewing that as part of the process of verification for the NHPCB submission process.

- (46:27) Should those who submit comments expect to receive a reply regarding what has transpired from that input?
  - **Todd:** We've received so many comments. We always acknowledge that we receive their comments and thank them. However, we have not been responding in depth to individual comments from people that would be overwhelming to try to do. Most accreditation and certification bodies when they're in an open review process do receive comments from a wide variety of stakeholders but do not specifically respond to each specific comment that is made.

- (47:20) Talk about the costs and is this going to be an extra burden for manufacturers to cover the cost of the seal?
  - **Mike:** So, I guess the short answer is yes, it will adjust your cost at some level. But I think the benefits so significantly outweigh that cost. Our industry has operated at a very lean level. Incredibly affordable for an immensely long period of time. Unfortunately, the pressures that we face today, tomorrow and into the future, in order to find our way to compliance, whether it's just simple current good manufacturing practice or it is in order

to obtain certifications, they are costs of doing business and if we want to be respected, if we want to be in an industry that thrives on being beneficial then we have to be able to burden that expense.

- (48:56) How much importance to the FDA will it mean if there are many manufacturers or brand owners engaged with this seal process?
    - **Mike:** For me, I believe that there's strength in numbers. Everybody I'm sure has heard that many many times. The bringing of industry, consumer, medical, you name it, across the board together is the single most important thing that we can do in this industry today, right now. I believe that the industry focus for the FDA right now is the manufacturers. We are a single point of failure. There's just not a lot of us out there and so they are focusing on us and if we can't withstand the charge, then we're in trouble and we're in trouble as a whole. I know there's competition and all of those wonderful things out there but this isn't about competition. This is about survivability. This is about our industry, and I can think of no more valiant cause for us all to rally behind. And so that's my response.

- (50:46) Can you tell us the difference between the HAERS and the FAERS or the Homeopathic Adverse Event Reporting System and the existing FAERS (FDA Adverse Event Reporting System).
    - **Todd:** One of the things that the FDA likes is data. Especially quality data. The FAERS has been in existence for quite some time and it's a helpful tool for the FDA.
    - One of the challenges of the FAERS is that it's open to the public and it's open to viewing by the public and as a consequence of that, it cannot include proprietary information about the companies.
    - There is no information in the FAERS database on, for example, number of units sold. This is a critical issue because there's a significant difference for example, between, say, the relative safety of a homeopathic product that has five serious adverse events for 100 units sold, compared to a product that has five serious adverse events for 10 million units sold. And so, one of the things that we want to do is to begin to pair data on the number of units sold. This is something that other healthcare sectors have started doing, creating more robust systems than the FAERS and the FDA has found this quite useful. For example, recently in speaking to the NASC, they had gotten a concern from the FDA about particular ingredients in animal health products and they went to their Adverse event database and they were able to demonstrate to the FDA that the number of incidents compared to the number of units sold was extraordinarily low. Based on that data that they did provide to the FDA, the FDA backed off on their concern about the particular ingredient and didn't pursue it.
    - Providing robust data to regulatory authorities can be beneficial in demonstrating the relative safety of particular ingredients overtime. The other issue about the FAERS database, (I could spend hours talking about this) is that the quality of the data is not good. There are many ingredients that are reported as homeopathic in the FAERS database that are actually not homeopathic. Often, they're herbal or something like that, and so they're misconstrued -the relative risk of safety.

- They're also not good definitions of ingredients in combination products versus single products. And so that's something that we can provide There's a number of other things, but I think the bottom line is that we can provide, like other sectors of the healthcare industry, a more robust view of adverse events and help the FDA with that.

- (55:10) There's a tag along question to that…Will HAERS be mandatory? FAERS is required by regulation. If not, how can one be certain that the overall information is complete? If yes, how will that mandatory participation be enforced or checked?
  - **Todd:** Like the National Healthcare Product Certification Board submissions are going to be entirely voluntary. It will be part of the application process but not all companies will be submitting data or submitting applications to the NHPCB. Those companies that will be submitting data, that data will then become part of the HAERS database as we continue to move forward. The larger the participation by industry, the more robust that database will become and the more effective it will be in affecting regulatory authorities.
  - Central to this process is going to be parity and reporting and so one of the things that we will be reviewing is how companies handle adverse event reporting and working to ensure that there is parity in all companies that are providing adverse event reports so that there's consistency across the industry and how this data is entered into the system.
  - (Note–added to original transcript) We plan to have a system in place where we have fake reports given to companies and then we see if they show up in HAERS. They would then be removed, but it would serve as accountability to the companies' reporting.

- (56:48) Will the initial focus of the seal primarily be on building consumer confidence in certified products or providing pushback to the FDA over the new guidance? What are the priorities?
  - **Todd:** For me the FDA is responsible to the consumer. At the end of the day, that's what drives the FDA and so I am not sure those can be pulled apart because for me they go together. The more that we restore confidence for the consumer and homeopathic products, the more impact that will have on the FDA ultimately. But that's just my view on it and I'd love to hear what Betsy has to say on this.
  - **Betsy:** The evidence is that consumers do not have a lot of concerns about the safety of homeopathic products. The market's been growing. Consumers are increasingly using homeopathic products. They seem to be very comfortable that they are safe and that they're useful to them and of value. The concern for the continued access by consumers to the full range of homeopathic medicines is their primary concern. It's not safety or validation or verification, it is, are they going to be able to continue to get the medicines that they want and that they're interested in and that they find valuable and that they rely on and for that the National Homeopathic Certification Board is primarily focused toward the regulatory environment because it is the regulatory environment currently that is threatening consumer access to these products.
- (59:20) Can there be a mechanism within the organization to report fake homeopathic products to the FDA? i.e. herbal medicines listed as homeopathic.
  - **Betsy**: The board does not have within its mission a policing function over the industry. It's a voluntary participatory process, and it can say these are the products for whom

the board's review has been requested and these are the products that passed the board's review and the companies that passed the application process and registration process. Any such products of course would not be eligible to bear the seal. But whether there are products like that on the market they should be reported to the FDA correctly. The FDA has a system for reporting those things.

- (1:00:33) How will the seal benefit retailers?
  - **Mike:** I'd like to think that the retailers having the knowledge of the products; efficacy, compliance and things like that puts a retailer in a better position. I think everybody saw two big retailers got popped yesterday and it's among several ongoing issues that they're dealing with and right now they don't, other than the legal side of the battle, they do not have something to hang their hat on. Similar to the industry, we have nothing to hang our hat on. I can't say, well here, CBG 400.400 says " X". All of that has been stripped. If we get our stuff together that uniformly helps us define what homeopathy in the future will be. And how it will be managed, how it will be regulated. How it will be certified. I don't know why a retailer would be taken aback by that or be harmed by it?

- (1:02:08) What happens when the FDA sends a warning letter to a company that has the seal for the product that receives the warning? Does the NH PCB help?
  - **Todd:** One of the things that is present for the Seal is a substantive change process. And what this means is that you're granted the seal for a period of three years for your products. However, if something happens, either to the product or to the company that is a substantive change (and we define what those things are) then they are required to report back to the NHPCB about what the issues and problems are. There's a separate application they have to submit about that process. So a warning letter would constitute a substantive change for the company. They would need to let us know. I can't speak to the helping, that's not the function of the NHPCB, to assist organizations. However, as we begin to have a greater seat at the table with the FDA, we can begin to take on a function of educating the FDA about homeopathy and healthcare products and that kind of thing. And I can say that in working with other organizations like the NASC and other similar seal organizations, when companies would get into trouble, they have had a voice historically with the FDA that has proven beneficial. So, I think that's going to take a while. Right now, we're just beginning to establish a relationship with the FDA. But I think down the line that we may be more and more effective in creating an open dialogue with the FDA about issues and concerns in the marketplace.

- (1:04:50) Has the National Homeopathic Product Certification Board any research which indicates that having a seal on one's product label will have any effect on sales? And if so, can that research be shared with the industry as it would be of utmost importance in making decisions regarding participation and ponying up the registration fees?
  - **Mike**: I'm not going to be able to speak to the research. Todd would have to weigh in on that. But I can tell you that today the requirements for being in mass distribution are accompanied by a requirement to have third party certifications. So whether that be

NSF UL or Intertech, (there's several organizations, they vary and change which is interesting), but ultimately that's the requirement of the retailer. The seal is (and again I can only speak from my perception of this) should be a requirement of our consumers. The consumers are what makes our industry thrive. The consumers are what makes our practitioners successful. The consumers are the only reason that we exist today and so Yes, I think it will be meaningful. I don't know that it should be a quote -unquote sole marketing tool. It has to have meaning. I've spent many, many months talking about the meaning of the seal. What does it mean? It means different things to different groups, but ultimately it has to mean that our application of that seal on your product means that you have withstood along with your manufacturer (if you're a brand owner) that push to make certain that you are CGMP compliant. That you do have your ducks in a row when it comes to the formulation or contraindication. I mean, it goes on and on the level of detail that we will bring to the evaluation of a product. And so, that's where I'm at. And Todd, maybe you can speak to research.

- **Todd:** We have not conducted research to date. Doing that kind of research, and that is something that we've talked about, would be very difficult to do in advance of having a seal. However, we do plan on conducting that kind of research as we get going with the project and trying to answer that question.
- How valuable is the seal to companies? One of the ways that we're providing value is we are providing a public database of all certified homeopathic seal products that will be publicly available.
- We will be marketing to consumers that if you're looking for a certified homeopathic product, then here are the companies you can go to to get the products or to the retailers that carry those products. So that will provide a direct benefit to those companies.
- I can also say, to this question, that we have talked to other seal organizations about this question, and they have all said to us that it has provided significant marketing value to their companies that participate in the SEAL project. So, for example, the non-GMO project, that seal provides added value on their products and increases their sales. This is what we've been told, and similarly with the NASC seal, for the National Animal Supplement Council. So just to review, we have not conducted research today. We are planning on doing so, and as we scan the industry that uses similar seal projects it appears that this is valuable to industry in terms of marketing and sales.

- (1:10:26) If a substance is not in the HPUS to what standards would the NHPCB be verifying the product it adheres?
  - **Todd:** That is a wonderful question and one that we have not yet addressed. That is going to be related to pathway #3 and pathway #4 which are going to be discussions down the line. We have decided not to deal with that right now because that's going to be a much more challenging question that we're going to try to address and answer. I do believe at the end of the day it's a question that we do need to answer because so many homeopathic products in the marketplace contain ingredients that are not listed in HPUS. It's important that that question be looked at. But we have not yet done that. And as we go through our process of creating standards for substances not listed in

HPUS, we will be opening this to the community again as part of our review process and seeking input and advice.

- Is there any reason as to why nasal products will be initially excluded?
    - **Todd:** There was a whole series of categories of products that we looked at. One was ophthalmic. One was otic, intrarectal, IV, intramuscular. There are lots of different routes of administration that we considered initially. We decided to start more simply with where the bulk of homeopathic medicines are. We recognized that other types of administration may require different standards and at the time we weren't prepared to review and create those standards. So, we decided to start simply, that being said, we are planning to eventually create standards for the full array of homeopathic medicines. It's just that we haven't gotten there yet and we're taking it one step at a time.

- How will the actual verification be handled? What will it be based upon self-attestation? How will the NHPCB actually verify that the truth is being stated in applications? Do the 30 or so NHPCB volunteers who are involved have the technical expertise to actually know what complies with regulatory requirements?
    - **Todd:** We have not yet composed or created the Application Review Committees, which will be reviewing the actual applications. On those committees we will have experts who are qualified to review applications. We also are planning to have a wide variety of consultants with technical expertise who will be available to Application Committee Review members to consult with on issues and ask questions as they arise. So that is something that we're just beginning to work on - to populate those committees and find individuals with the requisite expertise.

- (1:14:35) As a retailer, how would we convince our overseas manufacturers to participate in the seal process?
    - Mike: OK, so, I don't know how to convince anybody to do anything other than to not buy their products. I mean that's a pretty simple way to do it. And then they find the need. That's kind of a harsh way of saying it but if the seal means something to the consumer, if the seal means something to the public at large, they're going to gravitate to that seal, which would cause others to participate in the project. There's going to be people who do not participate in the seal and I don't know that they'll all be overseas. If we have the support of the consumer, the industry, the Food and Drug Administration and all those things I think that the importance of that seal will resonate to a point where it's desired.

- (1:15:59)Have you updated or changed your fundraising?
    - **Todd:** Fundraising has been targeted at achieving grants, working with foundations, and private donors. And we have been fairly successful in raising funds for the project that have seen us through the last three years as we've moved forward. We are in the process of constituting a fundraising committee, signing a chair and members of the committee that will be pursuing fundraising moving forward. That committee will be extending our reach in terms of grants and foundations and working towards legacy donations, which will be important for our future as well as working with the public and

donations. So perhaps crowdfunding as a source of achieving fundraising as we continue to move forward. So yes, our scope for fundraising today has been fairly narrow in its scope and focus and I think we're at the point now where we will be broadening our reach and scope for fundraising as we move forward.

- Does anyone else from the board want to add anything?
  - **Mike:** I'll do a little soapbox for everybody. I know the members of the board appreciate that. You know, as members of industry the time is now.. I don't know that I can say that loud enough. I don't know that I can champion a more important cause right now. We all have our companies. We have our organizations. We have all of that. But if we don't bring it together, if we don't all see the good in each and every effort and every attempt at getting our industry put together so that we can all find the success together we're going to be in trouble. I'm not trying to pervade gloom and doom. But reality is starting to hit very quickly and very hard. I can tell you sitting here this evening that I know that the Food and Drug Administration is in a facility at this point in time, doing an inspection on a homeopathic provider. I know that last week they were in another one and so they are continuing to make their rounds and we have got to find our footing as a group so that we can make enough noise that everybody's paying attention to us at the right levels. That's my soapbox.

- **Ron:** Thank you everyone for attending tonight and we look forward to hearing from you on our website with questions or comments. Don't forget to look at our site which is www.certifiedhomeopathic.org.

Goodnight.