



NABP 109th Annual Meeting
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St Louis, MO

Report of the Executive Director/Secretary

Presented by:

Carmen A. Catizone, Executive Director/Secretary



Thank you, Mike. My thanks to the Executive Committee, staff, and all the members.
President

Mike Burluson and the Executive Committee have been very supportive throughout the years. They have been over all of the 28 years that I have been with NABP. Mike's support even extends to helping me with my presentation today. He is actively soliciting someone to pull the fire alarm. I have heard him ask three people already about doing that.

This morning at breakfast, someone was talking about our Annual Meeting, and they had mentioned something that I felt was very true that I wanted to share with you. They said this was a good meeting. They said it was a good meeting because everyone seems to know each other. And if somebody really does not know anyone, people take them under their guard and help that person become very familiar very quickly. It is

a testament to all of you about how welcoming you are and how welcoming the Association is. They said what makes the meeting good is that people just seem to continue from last year's meeting or the meetings before from where they left off. It is almost like a reunion every year of people getting together and sharing thoughts. And again, a testament to the character of the board of pharmacy members and how you care about other people and how you embrace people and try to help people.

This morning, I want to talk about two issues. One of the issues is compounding and what NABP is doing to assist you. As I prepare my remarks, what I try to do every year is look outside of pharmacy, what is happening in the world, and look at what those challenges are, what those opportunities are, and what extends beyond pharmacy. This approach helps me to stay focused and look beyond the types of things we see every day. And when I do so, it has taught me a couple of valuable lessons. And one of those lessons is that there are touch points in all of our lives.

Those touch points, without any prior notice or rational explanation, confront us. Fate causes us to stop and change the courses of our lives from what we have chosen. The courses that we have been traveling on for so long, they seem comfortable, they seem familiar. And we felt the right courses for us are suddenly challenged. We ask ourselves questions like, "Why?" And "Why now?" Although we realize at the time what is happening, we are really not sure of the ramifications of what we are going to do or how what we are going to do is going to change our past, our future, and our present. It is at these touch points, that singular opportunity when faith comes knocking and stands before us that ultimately defines who we are and who we were meant to be. In fact, what we do at those touch points or those turning points ultimately changes our lives instantly and forever.

The past year brought to us, both as individuals and at boards of pharmacy, some disturbing and notable turning points. The events at the Boston Marathon and the explosion in west Texas.

As individuals, we were taken back, and those events shook our very essence. Instantly we saw that lives were lost and innocence was taken. What once was would be nevermore. Today and for many days of the future, our thoughts and prayers will remain for those who died, were injured, and continue to suffer either in pain or from the loss of a loved one.

For boards of pharmacy, one of those touch points was a sterile product contamination. We saw lives that were lost, people that were injured, and people that continue to suffer from that tragedy. As boards of pharmacy members and staff, you were faced with one of those touch points. One of those challenges. That touch point is testing how you respond and how you manage not only in immediate crisis, but how do you move forward to prevent future outbreaks as a board and as an individual? As Chef Jeff talked about, what is your legacy? Beyond what your day-to-day responsibilities are, what is going to be your contribution? What we saw was an incredible response. The states acted to address the situation in your state. You worked and are working to make some very necessary changes to address compounding practice and a regulation of compounding sterile, nonsterile across the board. In Saturday's session, we tried to provide an update, provide some varying opinions and give you some of the facts to date what was happening. The question is, though, what happens next?

In many states, the lights have shone very brightly on this issue on the boards of pharmacy. State legislatures and governors have been more than willing to give the board resources. What happens when the lights dim? What happens as we are seeing in states even today when the legislature or governors say, "We need those funds for other purposes?" Another crisis has hit. And so the money that has been committed for inspectors, additional staff, is suddenly withdrawn, and the boards of pharmacy are left with the same responsibilities, and now these enhanced responsibilities to manage the compounding situation.

One of the other next steps that is going to happen is that there is going to be some federal legislation. Many of you are familiar with the Senate HELP Committee – Health, Education, Labor, and Pensions – and the bill they have proposed. The Executive Committee has reviewed the bill, and I think everybody will agree it is far from perfect. But I could tell you from the review and work that the Executive Committee has done: that bill addresses almost every concern that the state boards of pharmacy raised. The Senate Committee listened to everything you said and took it to heart. They respect the role of the boards of pharmacy. They respect the autonomy that you need to deal with this issue. They know you need resources. And they have written this bill with all those in mind.

Now we can argue about what happened, who is right, who

is wrong, whether the bill is perfect, how do we fix it before it moves forward. But that is not going to work today, and it may not work when the House takes the issue. And the House bill may be dramatically different. It may try to take authority away from the states and create a situation that is even worse than what we have today. So the Executive Committee has indicated that they are going to send a letter of support to the Senate HELP Committee recognizing that there are still some things that need to be addressed, but at least recognizing that this bill goes farther than any bill has gone in the past and truly is representative of the concerns that you have brought. We ask that you talk with your senators and representatives and voice a similar opinion or at least express support for those major components of the bill so we can get something that makes sense and to have something that will help us all move forward together.

That was the other lesson that we learned through this whole situation. There is no one person, no one board with the expertise, resources, and ability to prevent such an event from occurring again. There is no board or entity with the expertise, resources, or ability to manage and respond to such an event independently and isolated from other boards of pharmacy. To this end, NABP has embarked on a very aggressive initiative that the Executive Committee has said we need to move fast to implement, and that is the creation of an NABP

e-Profile for every pharmacy in the United States.

Similar to the profiles that we have created for pharmacists with the CPE Monitor® program, we are actively collecting information on pharmacies and will make that information available to all state boards of pharmacy electronically. We presently have 280,000 profiles for pharmacists and believe the total number of licensed pharmacists in the United States is probably 320,000 individuals. That is how close we are with having a profile for every pharmacist in the entire country. We will soon have a database based upon the inspections that NABP is conducting with the Iowa Board of Pharmacy and the other boards where those pharmacies are domiciled and any of the inspections that you are doing in that database. That database will address one of the critical deficiencies that the sterile product contamination identified. There was limited information on those pharmacies. It was not being shared. When it was shared, people really did not know what to do with that information, did not realize the ramifications of some of the actions that the states took.

And so what we have tried to do is address that by building this database that is going to house all the information you are going to need to make a decision on whether or not to license or renew the license of a pharmacy, whether it is a nonresident pharmacy or whether it is a resident pharmacy that you need assistance with. And what we

are ultimately going to create is a type of license and verification and validation system for pharmacies that we now have for pharmacists.

Imagine how helpful it would be to have that information compared to what we have been doing to date. There has been little or no information on nonresident pharmacies. You have relied upon each other. But those states where those pharmacies have been based have not had the resources to inspect them, and so you have had to make decisions on those nonresident pharmacies with virtually no information except the fact that they held a license in another state. All the states realize that that was not enough. That they wanted to inspect those pharmacies on a regular basis, that they needed to inspect them, and that the old, "Trust me, I'm doing a good job in those pharmacies" no longer exists. We cannot go back to the old system. We are hoping that this new system addresses that and helps you with all those questions.

In regard to the inspections that we have done and where we are moving with that phase of the program as well, as Lloyd Jessen mentioned on Saturday, Iowa has approximately 600 nonresident pharmacies. We have already inspected over 100 or so. We are averaging 50 or 20 a week. I think there are 43 states where the nonresident pharmacies are located. Right now we are negotiating a contract with another state to help them with the inspection and review of 150 compounding pharmacies

in their state. Two other states have passed legislation that will allow that state board of pharmacy to use a third party to conduct inspections for them. And other states have approached us and said, "We have a nonresident pharmacy in this state. We've talked to that home board of pharmacy about that particular pharmacy and asked them to inspect it for us. Because we suspect there are some problems there." And that board has responded, "I'd love to get out there and do that. I don't have any resources. By the time I schedule a visit, it's going to be six months because the investigators or inspectors that I use have to be used for all the other programs and I can't get them into that pharmacy. Or the inspectors and investigators that I have available to me have no expertise in sterile compounding." So they have approached NABP and said, "Would we be able to do this?" And the answer is yes.

Whatever assistance we can provide to the states to address that other concern, the Executive Committee has charged us to make sure we provide that assistance and those resources. At your fingertips at an electronic database, you will have every licensed pharmacy in the US. It will have demographic information, business information, and hopefully inspection reports from every state or from the state where that pharmacy is located. If we cannot release that inspection report, or you cannot share it with NABP, then we

will have a message in there for you so that you will know that something has occurred at that pharmacy, and as state agencies, you can communicate directly and get the information you need to make a much more informed decision. That information was not available. It is going to be available, and we hope it will help prevent another sterile product contamination or another problem in pharmacy practice.

We are excited because the responsibilities that you have that have grown will finally receive some assistance in a way that we hope will be meaningful to you. The possibilities are endless. The cooperation and effectiveness with the boards of pharmacy are unlimited and the protection

of the public health that you as boards of pharmacy provide will become more consistent, more permanent, more uniform, and unsurpassed by any other licensing agency. We are moving forward aggressively. The system is already operational. We just want you to provide the data and cooperation that we need so that your colleagues in other states will be able to share that information and have access to it.

The other side of the coin, the stark realization is that if we do not change, if something else happens, there will be more hearings. There will be more accusations. And the focus will be on the boards of pharmacy. And we are not sure what the

resulting legislation will be if that occurs again. We want to be proactive. We want to prevent that situation occurring again. We want to put a permanency to what you are doing by providing you the resources you need and making sure when those lights dim and they begin to scale back resources and leave you in the same spot you were before the tragedy that we have changed that landscape and that NABP is there to provide the resources you need and the support you need so that you can remain strong, maintain your authority, and, working together, can do what none of us can do alone. Thank you.