



Report of the Executive Committee

NABP 113th Annual Meeting
May 20-23, 2017
Orlando, FL

Presented by:

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Good afternoon. Those of you who have attended recent Annual Meetings know that I've utilized

various methods to drive my message. I would ask you to read aloud words on the screen, I would speak to you from the substage, or have you stand up. At last year's meeting, and again, just now, as I walked to the podium, you heard music from U-2. I use U-2 not because I'm Irish, and U-2 is comprised of four Irish musicians, but their music is a lively and fun illustration of great things that can be accomplished by a small, stellar group working together. The National Association of Boards of Pharmacy® (NABP®), like the musical group U-2, though relatively small in numbers, is well respected in the regulatory community, and we continually work hard to orchestrate and deliver resources and services to assist our member boards in their mission to protect the public.

It's hard to believe it's been seven years since I began my service on the executive committee. There have certainly been many changes in that time – changes in the practice of pharmacy, changes in the political climate, and changes in the Association. With technological advancements and expanding scopes, the practice of pharmacy continues evolving, bringing both new opportunities and new challenges to regulators. With the promise of fewer regulations at the federal level, it is all but certain that the states will need to increase their regulatory efforts. Undeniably, our mission as state boards of pharmacy to protect the public health is more important than ever. And appropriately, the shifts we have seen sync with our meeting theme, which focuses on imagineering new solutions to the shared challenges we face as state regulators.

Before I share how the Association's 2016 efforts reflect this theme, I would like to take a few minutes to remember three true imagineers, former NABP Executive Committee

member, John Foust; former NABP President, David Work; and former NABP honorary president, Sister Margaret [Wright]. Sadly, John, David, and Sister Margaret passed away in the past year. John Foust was a fellow Executive Committee member. His debilitating illness struck shortly after he was elected to the Executive Committee in 2015. John was very accomplished professionally, having practiced pharmacy for over 30 years before serving as executive director of the Oklahoma Board of Pharmacy. His leadership at the Oklahoma Board of Pharmacy in efforts to bring awareness to the public about the growing epidemic of prescription drug abuse through the video "The Road to Nowhere," and his distribution of the Pharmacist Pledge to raise awareness regarding the misuse and abuse of prescription drugs to the pharmacists in Oklahoma were two powerful examples that demonstrated his deep commitment, as both a regulator, and a good and caring man, to make a meaningful difference in the lives of others.

John loved to travel and spend time with his family, including his “extended” family through the Boy Scouts.

David was the executive director of the North Carolina Board of Pharmacy for 30 years, and served as NABP President in 1993. Sister Margaret was a member of the Illinois Board of Pharmacy, and an active NABP member who served on several task forces and committees and consulted on the Survey of Pharmacy Law. John, David, and Sister Margaret’s leadership and accomplishments in pharmacy practice and regulatory matters, and in the Association, remain an example to us all. I invite you now to share a moment of silence in honor of John, David, and Sister Margaret’s memory.

On Tuesday afternoon we will present a recognition resolution honoring all NABP members who passed away in the last year. In addition, we will have another opportunity to honor John during our awards ceremony on Tuesday evening. John’s daughter Caroline is here and will be attending the awards ceremony.

As I mentioned, our theme focuses on the power of imagineering and specifically three aspects of imagineering: explore, discover, act. The successes of 2016 illustrate that the Association has lived out all three aspects in the past year. Now the last verb “act” is also a challenge for all of us as regulators. Through NABP we have been and must continue to be creative, to “explore” and “discover” new solutions for

our common challenges. But we must also “act.”

“Ok,” you might say “That sounds great. But what more can we do as state regulators?” You might be thinking about how your board’s time, staff, and resources are already being stretched to capacity. I know this because in my time serving on the Executive Committee, many of you have shared these challenges with me.

So now, in my final speech as an officer of the NABP Executive Committee, I feel it’s my responsibility to remind you how the many programs and services offered by the Association address the question of what member boards can do. These programs are in place and ready to assist you in taking action.

I would like to review the 2016 successes of just a few of these programs and the results that can happen when we explore and discover together. And I will circle back to note specific actions that each of us can now take.

2016 saw several advances in an existing area – NABP examination programs. You may have seen the article in about the Association being granted a patent for the Outlier Detection Tool, a methodology that allows test results to be analyzed for any performance outliers or irregular response patterns. In addition, NABP’s proprietary test assembly method was deployed to the North American Pharmacist Licensure Examination® (NAPLEX®) in November 2016 after

successful use in the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) the Pharmacy Curriculum Outcomes Assessment® and the Pre-FPGEE® and Pre-NAPLEX®. These changes enhance the Association’s continued efforts to ensure the validity, integrity, and security of the examination programs.

Further imagineering our way to the future, the Association also launched the Verified-Accredited Device Integrity Program (VDIP). This new accreditation addresses entities that distribute certain over-the-counter diagnostic medical devices to pharmacies. With threats to public safety from gray market distributors of products such as diabetes medical supplies, NABP saw the need to develop this new accreditation.

The Association’s experience with the Verified-Accredited Wholesale Distributors® program provided the necessary expertise for staff to develop the standards and processes and launch VDIP at the end of 2016.

The services provided to help ensure the safety of compounded medications also clearly demonstrate what NABP members accomplish when we explore and discover the answers together. In 2012, when I was serving as a member of the executive committee, the New England Compounding Center tragedy struck, involving the distribution of contaminated compounded steroid injections that led to an outbreak of fungal meningitis. As you may recall, hundreds of

patients were harmed and 77 patients died after receiving the medication. Since that time the NABP members have come together at forums, workshops, and United States Food and Drug Administration meetings to share insights and develop a means to help prevent such a health crisis from occurring again. Many of you were involved in those meetings and contributed to development of NABP services such as the Verified Pharmacy Program® (VPP®), the Multistate Pharmacy Inspection Blueprint, and the Universal Inspection Form.

Here's a snapshot of what's happened with each of those services in 2016.

As you know, VPP is an inspection and licensing service for pharmacies. They apply to have a qualified inspection completed, licensure data verified, and a disciplinary check conducted against the NABP Clearinghouse. The results of this review are stored in the NABP e-Profile Connect system so that boards can access data on pharmacies applying for licensure to dispense into their state. As of May 2017, 46 state boards of pharmacy recognize a VPP inspection as meeting their state's nonresident pharmacy requirements. In addition, about 700 pharmacies have applied to VPP. Verified data for these pharmacies is currently or soon will be available for boards of pharmacy to access in NABP e-Profile Connect when making licensure decisions.

Further, multi-state chain pharmacies have applied through VPP, making the

program an even more robust source of licensure data. I also want to remind you that VPP inspections were developed as an interim solution until the boards could implement any needed changes in their own inspection processes or to supplement existing board processes and inspections. Further, VPP data is not the only information stored in NABP e-Profile Connect. Authorized board staff may access inspection reports from other states, disciplinary data, pharmacist-in-charge information, or other data relevant to licensure in your state.

To help create uniform criteria for state inspections, almost all member boards participated in creating the Multistate Pharmacy Inspection Blueprint. The hope is that as a regulator, if I'm reviewing an application from a pharmacy licensed in another state, then I can utilize inspection information reported by the state of original licensure. And in addition, I can be confident that an agreed-upon baseline of standards was used in that inspection.

To reach this goal of greater uniformity in inspection data, NABP now offers several resources as part of the Multistate Pharmacy Inspection Blueprint Program launched at the end of 2016. These resources include the Universal Inspection Form, the crosswalk to the Blueprint, and inspector training specific to compounding.

Now here's where I can provide some specifics on what further

action your board may take to continue on the road to compounding safety. There are three actions your board can take.

Number one, consider becoming a Blueprint state. To do so either,

- A. Incorporate the Universal Inspection Form into your state's inspection processes, at least for those sterile compounding pharmacies shipping into other states. Or
- B. Submit your sterile compounding inspection form to be crosswalked by NABP staff with the relevant sections of the Multistate Pharmacy Inspection Blueprint, and make any suggested changes or additions as needed.

I remind you again that the Multistate Pharmacy Inspection Blueprint and the Universal Inspection Form were created by the member boards for use by the member boards. In fact, the Universal Inspection Form, which was based on the VPP inspections for sterile compounding and incorporates USP 797 standards, was field-tested by a number of member boards. Those boards made suggestions for improvements and the form became available to all boards in November 2016.

Currently, nine states are designated as "Blueprint states" and NABP Member Relations and Government Affairs staff are currently in discussion or working with 18 member boards to utilize the

Universal Inspection Form or crosswalk their processes to the Blueprint. Member Relations and Government Affairs staff will be reaching out to other boards in the coming months and are available to assist your board on the path to becoming a Blueprint state. Doing so signals that sterile compounding pharmacies that ship product out of your state are being routinely inspected and that the resulting report reflects robust standards, uniform among the states.

Number 2, take advantage of training for your inspectors and compliance officers. NABP has made available two training options for these staff. They may attend compounding inspector training at the Critical Point training facility in New Jersey, with NABP covering the costs for tuition and some incidental costs for a total up to \$1,995 per approved board attendee. Or boards may contact NABP to request training in the field. In this case, an NABP inspector travels with board staff on a determined number of inspections to provide training based on the Universal Inspection Form. NABP has received a grant from Pew Charitable Trusts to support the provision of in-the-field training for a total of 15 member boards over 2017 and 2018. On behalf of the Association, I extend our thanks to Pew for supporting these important efforts. Both the Critical Point training and the NABP training include how to inspect for compliance with USP 797 and USP 800 standards.

Number 3, utilize the data in NABP e-Profile Connect and, if allowed by your state, upload your board's data for others to consult. As mentioned, e-Profile Connect contains state inspection reports, VPP reports, and verified licensure data. If you have any questions on using e-Profile Connect, please reach out to NABP.

Again, the 3 steps you can take are:

1. Become a Blueprint state
2. Train inspection staff
3. Utilize e-Profile Connect

And now I would like to show a short video sharing comments on these services from a few member boards. Thank you.