

AACP: Embracing the PBRN Model to Improve the Medication Use  
Process  
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**Keynote Address - 1.5 Million Reasons to Improve Medication Use**

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PharmacoEconomic Research Center (HOPE).

**Earlene Lipowski**: Before I moved on to, and I almost forgot. When the money—we actually found out and got the funding from our—about three weeks ago, a little over three weeks ago, and at the last minute we were able to find the resources to bring in DigiScript to do the filming. It's something that the board had been talking about wanting to do in order to be more responsive to members' needs, to be able to capture things so that people who aren't able to travel and be together can somehow share. We have a tremendous morning of assembly of people. I'm not sure we can get all those great people into the same room at the same time again, and so I'm really delighted. And the DigiScript people are very professional. They are going to be quietly working in the background and other than the lights in everybody's face which we've been complaining about. It's been a pleasure to work with them. I want to thank them for being there.

I'd like to—before we introduce our first speaker, take a few minutes to discuss what's in that binder that you picked up last night. We want to make sure that you bring it to all of the sessions. We knew that there were people here who had been thinking about practice-based research and been engaged for a long time. But we wanted to turn this into a session where we question and challenge and make you rethink all the things you think you already know. So one of the ways we're going to do that is to use the talents that are developed with leaders in quality and innovation to help us think creatively.

And what it means is that all of us are going to have to go with the flow. We're going to have to understand that sometimes it's going to be an uncomfortable process and sometimes we're wondering where is this all leading and how is it all going to come together, but it will. And we're going to leave here tomorrow with, I hope, some crystallized ideas and some action plans that we can get to work on and actually take our ideas forward and move on to the next step. So it's not your typical meeting. We do have some plenary sessions to get us all on the same page this morning. But then after lunch it's really roll up your sleeves and get to work. And we will come to this resolve, a set of action plans that we promise you'll be taking something home that you can act on.

It's my pleasure now though to introduce our keynote speaker, Dr. J. Lyle Bootman, dean of the University of Arizona College of Pharmacy. He's also founder and executive director of the Center for Health Outcomes and Pharmacoeconomic Research, the HOPE research center. As you know, he was the co-chair at the recent IOM committee on preventing medication errors. He's former president of the American Pharmacist

Association and president emeritus of Pharmacy in Therapeutic Society. Dr. Bootman received his pharmacy education at the University of Arizona and his doctorate at the University of Minnesota. He's a widely published author and presenter at professional healthcare meetings and symposia. And he's going to share with us some of the thoughts that have come out of this highly publicized report, "Preventing Medication Errors." So Dr. Bootman, welcome.

**J. Lyle Bootman:** Well, thank you very much, Earlene, and, Lucinda, thank you for your introductory comments. It stimulated me further to try to stimulate all of you and get us thinking in this particular area. I was also very pleased, Lucinda, you added a few years to my life because we travel a lot, a lot of hotels and each time you get up another day you just, I'm starting to feel it a little bit in my age, but to find out that I always looked at Barry Carter as a contemporary, to find out that he's second generation added a few more years to my life nicely. So I'm here live and early even though in Arizona right now it's about 5:00 or 5:30. So I'll wake up sometime when this particular presentation's over.

It's also a very important, very pleased to be a part of this important meeting. As Lucinda mentioned, probably over my career, there have been several similar types of meetings that people came together, whether it was to discuss in the late '70s at the AACP, whether the profession should move toward an all PharmD degree as its basic entry level, or in 1985 at the Hilton Head conference, all of these serve as interesting small venue hotels, groups about this size, mental brain power coming together, solving and addressing the problem in an honest, direct manner. I look there and see Max and the many conferences that he's led over his career that fostered my thinking and moved us into this particular realm where we are today.

Lucinda is absolutely correct. There's probably no greater time in the history of healthcare or the pharmacy profession. The stars are aligning, and that medications, the proper use of that technology we call simply a drug, has received great deal of attention. Probably in the '50s and '60s post World War II it wasn't as dramatic. Drugs were \$.99 a hundred. There were a few that cured the sore throat, took care of a little bit of blood pressure, some more dangerous than others, but overall it was considered a technology, probably didn't even use the word technology. But today, and I can tell you that what our scientists are developing in the laboratories, the new drugs of the future, are extremely powerful agents that potentially can cure diabetes, cure disease, better diagnose disease, pinpoint disease, monitor disease. And our scientists, our basic scientists if you will, are doing a yeoman's type of a job putting—preparing us for the 21st century.

However, those of you in this room that, and those that we're going to stimulate outside this room and engage in this national, possibly international project, that will allow us to better apply and assure that this technology called a drug works, works relatively safe, monitored correctly, used appropriately, and indeed that most importantly it has an impact on disease. What the consumers expect, something that will help those baby boomers live another 5 or 10 years or 15 or 20 or forever in some of their minds, our minds, my mind, etc. So it's a very timely activity. We do—if I do nothing more than this morning to stimulate all of us on how we get our arms around the application, the safe

application and to developing the research that helps us better understand that application the better.

I think it's very important, however, to make sure the profession engages, that it is the profession for the docs in the room, I know Dr. Hickner is here, any other physicians? So I can look at him directly, a couple of you, straight ahead. That this is the only profession that dedicates itself around simply that technology called the drug from discovery, identifying the molecule, to developing it, to in those clinical trials and those areas that we refer to demonstrating efficacy, how it behaves in a more ideal type of a setting where patients comply and take it in the right dose, what we refer to as the clinical trial, FDA approves it, the von Eschenbachs sanction its approval. And of course it moves to the real world where the value basically is not attained. We don't attain value because folks don't take it appropriately, error occurs, medication-related situations that such as compliance and improper dosing, improper management. And we don't achieve control for diabetes and high blood pressure, those chronic disorders.

The time is here that this profession who's always embraced that type of technology - as the ones who helped to develop it, discover it, and apply - it can rise to the occasion and better understand that application. I believe it's, that's been the weak link. Not understanding the application side has probably affected dramatically our ability to properly manage, prescribe, dispense, but achieving proper outcome associated with that technology.

We're going to accomplish several objectives, but it's probably the fourth bullet that's most important to me, is the leadership necessary. Because all of everything I'm going to share most of you are probably very well aware, whether you're a junior assistant professors, or senior faculty, or the Max Rays of the world has been breathing and living this particular topic for a long, long time, thinking about the issues, how to solve and approach the problems. So the details of my talk are probably just to bring us at the same level of thinking. However, the leadership necessary is probably the most critical.

The amount of disease society in America will be confronted with over the next 20 to 30 years with the baby boomers aging and moving from that 39 million aged Americans to 80 plus, 79 million folks, if we were to line up all the docs, I don't know how many there are now, 700,000, all the nurses, over a million, 1.2 million, all the pharmacists, and gave them all an equal license to diagnose and treat disease, forget the barriers of state law, etc., there still would not be enough practitioners that are going to deal with the amount of disease, chronic disease, that need to manage it in a quality and safe manner that's going to confront us over the next 20 to 25 years.

It is really daunting, more than impressive on how we as a set of health professions are going to rise to this occasion. I suspect technology, informatics, things that I'm not really thinking about or very clear upon that are going to help us move through this in a more efficient manner than I'm thinking about. But I'm actually very fearful on how we as practitioners, those of who are training and educating practitioners, how we're really

going to rise to the occasion. I suspect the consumers will probably be on their own in many particular cases.

I start most of my presentations with this slide. I could actually speak for the next several hours if not days. I love this slide because everything revolves around trying to attain value. Docs, I'm being a little critical, I'll be a little cynical and critical today, but docs oftentimes tell me the dean of medicine, we're not interested in the cost dimensions of healthcare as much. There's some of us who are, but we like to diagnose disease and prescribe and monitor disease without cost concerns and what it actually cost. We just want to do the best. What they don't realize is better understanding the relationship of the cost of disease, the direct and indirect cost, the cost of interventions, the savings that drugs can provide if used appropriately. That dimension allows us—understanding the bottom quarter of this diagram allows us to better ensure access so that other people, more people, can have access to care and more treatments. If we better manage that technology simply the drug, for example, we can make sure that more people have access to the medication if necessary. So that you cannot ever separate the access dimension from cost and quality. And of course value is most important.

I bring this up just again many of you are very familiar with these types of statistics, the incidence of disease, these change and will continue to change. I believe this slide, some of these are slightly different. It's interesting to look at Alzheimer's, a disease that we see quite heavily in Arizona, increasing, the incidence, prevalence of Alzheimer's disease continues to climb in our society. We see that it's really only 4 million folks, maybe a little bit more than that today, at \$100 billion cost. You can see it's a dramatically costly disease, and this is just estimates of direct cost. You can see other diseases like cancer, twice the incidence, prevalence, a little bit more expensive, heart disease, etc. Medication mismanagement, as many of you are well aware of, those costly activities if we were to refer to that as a disease, some estimates bring that to as high as \$150 to \$170 billion of additional expenditures resulting from medication error and mismanagement of medications. It's right up there with cancer, Alzheimer's, even if you took the most conservative estimates it's around \$90 to \$100 billion. It's right there near Alzheimer's.

And of course we don't have the National Institute of Medication Errors, similar to the National Cancer Institute or the other institutes that dedicate themselves to identifying and solving that particular disease state. We don't have an institute that wraps itself around drug therapy and trying to improve. Of course, all the institutes think that they do something toward that end, but obviously at the hundreds of billions of dollars we spent on medical research over the last years we still have a pretty strong disease state called medical errors, medical related problems. It exists. In fact, I would claim that even despite a lot of our efforts and education in pharmacy over the last 50 years, that disease state continues to increase in complexity, severity, and cost.

We know through the IOM studies that basically about 15 conditions - this slide just reminds—account for about 50%, 56% of increased healthcare expended. This slide just reminds me that as we think about your research paradigm, you think about this PBRN model, we don't have to attack all disease, all situations. We can start to think about the

80/20 rule, the low hanging fruit. Where are the areas? Can the PBRN model, the pharmacy PBRN model, what are the areas that you can begin to think about a low hanging fruit? What are the areas that will make the biggest impact in which the editor of the New York Times will come visit you and say, "I want to know more about this study." Not necessarily the editor of the *New England Journal*, the editor of the New York Times. We see that you're making an impact on citizens, on consumers, on patients; now, we want to learn more about it. Then you know we've succeeded in this overall paradigm.

As Lucinda mentioned, much to the credit of a young lady, Janet Corrigan, some of you may know her name, you may not. She was the staffer, the director, that led the Quality Chasm Reports to the United States. Not a physician, not a pharmacist, not a nurse, not anyone in the healthcare field, but someone with probably the deepest passion and commitment to assuring quality healthcare of any individual I've ever met. Janet spent many years digesting on this topic, trying to convince Congress, the White House, the Institute of Medicine and its ways of doing business to take on this topic that they knew would lead to a very controversial, great deal of headline, etc. Of course, they released their first report, *To Err is Human*, which is the one that received most of the headline support because you know the way the media operates and the way they sell their newspapers, their technology, is through that type of headline approach.

*To Err is Human* received a great deal of press. The most well-written and insightful and guided treatise, however, was the *Crossing the Quality Chasm*. I believe that there's a lot of in-between the lines, hundreds of pages of how we can solve this problem. Much of it would be prescriptive to what we're trying to do in this room and taken outside of this room. So that's a great book if you've not read it. I'll try to summarize it on one slide, a few hundred pages. We'll move from there.

Several other types of reports, and we won't go through with them, of course, the report that I co-chaired with Linda Cronenwett from North Carolina, the dean of nursing here at the UNC, preventing medication errors was the sequence of the series. We'll talk a little bit more about that, but I again don't need to spend much time because all of you are probably very familiar and if you're not, you'll say, "Well, that's a no-brainer. We understand that. We've always understood that. The question I have is why is it still a problem? Why is it a growing problem despite all the actions we've put forth in our profession over the last several years?" And then the most recent report which continues to receive a little bit of attention. And, of course, Dr. von Eschenbach, the head of the FDA, he probably doesn't sleep seven nights a week as a result of that report trying to figure out how he's going to operationalize and revitalize change, re-engineer the FDA in this country. The one agency that actually we do confront with because it is that agency that finally sanctions that technology called a drug and says, "Hey, we can send this out to the real world because we've judged that it's relatively safe and efficacious." Dr. Hickner, we use the word efficacious because that's how that drug works under that ideal clinical trial, the 25,000 subjects, not how it behaves in the real world when there are millions of subjects who receive it and most of them don't take it to the proper length of time anyway. So we never do achieve value or effectiveness oftentimes, and sometimes

when they do comply we receive safety issues and problems that are related to that particular notion.

So we'll review a couple of these reports. Actually the Quality Chasm Report, if I were to distill it into six points, bullet points, this is basically it. There's some very important components in this. It's very detailed. I believe it's very prescriptive in terms of our research agenda dealing with medication use, etc., and you would see our report Preventing Medication Errors is somewhat parallel to some of this activity. I believe that consumer involvement is probably the one key, in principle. And that's where this PBRN model, as I've learned more and more about it in this link to the consumers, they are engaged, the ones engaged. I know that Rebecca Chater brought it up in her presentation last night in terms of engaging the consumer as a part of this research paradigm. Their participation, their involvement in the diagnosis and treatment of disease, and the proper management and monitoring of drug therapy.

And so we could dialog a great deal on all of this. Of course, the values that the Quality Chasm Report put forth for our healthcare system, that it's one that needs to be safe, effective, patient-centered, timely, efficient, equitable, is the key principles behind everything we do, and, of course, everything that you do relative to the medication product. I put safe there first because I think historically that's probably the one issue that consumers tell me that they're most thinking about relative to drugs. Of course they want it to lower their blood pressure, control their cholesterol, or diabetic control, etc., etc., but safety is the issue that they've always been worried about. That's why the FDA was formed in 1906 around the issue of safety. Many of the young folks don't realize that it wasn't until 1962 that the FDA was charged that you had to prove a drug was effective. For 60 years you only had to prove that you were relatively safe, not effective. They didn't care whether it worked or not, just that it was somewhat safe because consumers, society, was very fearful that pharmacists making those potions and giving those little pills having no idea what it was or what it does, how it's made, can affect you or not.

I remember growing up. I grew up in a community pharmacy in the '60s and '70s. Some of you that are my age would know that you could not put the name of the drug on the vial, on the label. It was against the law. You couldn't tell a patient what that was for. You needed to ask your physician. Pharmacists were not a point of that communication. You couldn't—that little insert you pull out when you pulled the vial or the patients, "Oh, I'd like to have that drug information." "Can't share that with you. Can't provide that information to you." That wasn't that long ago. I'm not too much in the dark ages, but it wasn't that long ago that you could not share that type of information with patients. We've come a long ways. And, of course, we have a technology that's much more complex.

The IOM helped us with an 80/20 rule. They began to look at those areas that really are the low hanging fruit, the problems, the priority areas that health professions, PBRNs, and folks who do research need to attend to, these particular areas in general. Interestingly, it's the last bullet that struck and helped me carve out the argument that medication management or mismanagement needs to become a focus, focal point, for the

IOM. Put some brain power behind what the issue is. Let's frame it, how extensive, and how do we move forward in remedying that particular problem. Of course, all of you in this room, every single one of you who are pharmacists, we have felt this, understood this, just as Lucinda said, it's been in our hearts and souls. We see it daily, the particular problems, but it's an issue that we've not really marshaled up and engineered the system and the approach, even though there are many CEOs of retail pharmacies, etc., who I personally have chatted with, and it is in their heart as consumers, their own mother, their own father, their own selves. They'd like to solve this problem and make sure that even themselves the house that they build is one that they live in - sort of symbology. They would like to really approach this problem, but how do they do it and still remain in business? How do they marshal those resources in a cost effective way?

So medication management has become on the marquee technology that needs to be put forth. Therefore, when I was successful in convincing Congress to make this a part of the CMS Part D package to examine it further, we were very fortunate to pull together a team. I must tell you that it wasn't only my credit. There were many folks behind the scene, but one particular person that was very key to the success of even getting Congress to say, "Okay, we will fund and we will charge CMS to doing this," was a fellow by the name of Mark Hayes. And some of you may know Mark. He's a pharmacist. I don't think he's practiced much in his career. He spent most of his time in Washington, D.C., from Missouri I believe originally, might be a UNKC graduate. Mark chaired the Senate Finance Committee as the chief staffer and he assured me that when the midnight hour came he had put in a few sentences in the law and we just get it done. And it got done and they charged the IOM. This is where I sort of take a break and explain and break down the myth.

The Institute of Medicine is not a government agency. It's completely independent. It's the only agency associated, it's actually a division of the National Academy of Sciences. National Academy of Sciences was formed in 1862 by Abe Lincoln. It was formed to be a completely independent, tell us the truth on whatever the issue is. Should we go to the moon? Should we explore geological phenomenon X? Should we solve healthcare problems? What are the issues? It was to be a—it's an independent agency that serves to advise Congress, the White House, the Supreme Court, the agencies, the major agencies in our U.S. government without any restrictions. It's the only agency that freedom of information, discovery by lawyers, there are exceptions and not allowed activities. Everything that we transcribe, we discuss, is kept in a vault somewhere in Washington they say a thousand feet below the surface, maybe below APhA's new headquarters. I'm not sure, or the State Department. But somewhere because the IOM is right next door to the APHA interestingly. So that it may be, maybe that's why it's taking long to dig the hole and figure out what's going where. Top secret I think.

But it's an interesting agency to work with. It's been a very much of a privilege in my career to be able to interact with those folks and see how they think, how they advise Congress and the White House, etc. They developed this national agenda or this approach to developing a national agenda. Did we accomplish it? To some degree. We did have some of the, I think some of the best minds in that room. Rebecca actually was a part of

that committee. She could probably attest that there are some pretty bright people that sit around that table. It didn't matter whether you were a physician, a nurse, a pharmacist, or a consumer. They all wanted to solve this problem, not just because they wanted to become famous or give speeches, etc., because they really every one of them had a story in their personal lives where someone was harmed or dealt with inappropriately with medications to the extent of death, to the extent of lowering quality of life, etc. Great deal of testimonials.

I can assure you that those types of personal case studies did not influence necessarily their overall thinking on how to get their arms around it. That's when their science hats went on, the rational thought, but they really, there was a true passion independent. This is general consumers. This is a serious issue. This is an issue. And there's no profession that's really rising to the occasion. Rebecca and I sort of put our hands up slowly and said, "Well, the pharmacy profession is sort of beating on this door for a long, long time, but we've really not gotten the attention of a lot of folks because they weren't, I guess, weren't convinced that it was a serious enough of a problem.

Of course, when you started it's sort of like when I had a college retreat or all of you participate in a retreat, you spend the first day of a two-day retreat just discussing the definition of a mission or the visions, frustrating to deans as well as to faculty and participants that you spend days and days on the wording of a mission. Well, we have the same type of dialog. It doesn't matter if it's the IOM. It's, I think, just part of organizational life. We've spent I don't know how many days just discussing this table. What's an error? What's an adverse event? What's a medication error? And everyone had their intellectual thought. Mine is real simple. If you're just not lowering blood pressure, you've got people who say it's a problem, it's a problem, whatever that situation particularly is.

We came forth with these definitions. The one that we're weaker on and one that received a great deal of controversy, it's remember that a failure—it's a failure of a planned action. We always think about and assume that the action is planned how we're going to treat disease, etc., is appropriate, but we found often many times that the plan was incorrect. We needed to take a different approach completely, maybe therapy was not advised drug therapy. In some cases there are many patients in which they weren't even in the system to get a particular therapy, an access related error.

The frequency, I don't really want to highlight all of these. I can also tell you though that you need to put on your conservative hat. These were the most conservative of all time estimates. And they are way too conservative in my particular mind, but they are still astounding, still nerve wracking, still kept you up at night as to who were those 1.5 million folks. And the notion that every patient on average in a hospital day engages in at least one medication error. Every day. I don't know how many people are hospitalized today in America, but I'm sure quite a few, many, many thousands of folks.

And if you think about the acute care setting, and move it to the ambulatory care arena, I can't imagine the true incidence of some type of medication related problem that

occurred this morning across this country if not across the world. It's, again, a statistic that we don't need to dwell on much more. There are those on our committee and task force that felt we needed to really pinpoint precisely how often this occurs every second in America. There are those of us like myself who thinks, oh, we've sort of studied the incidence to the hilt, we need to really start thinking about solutions. And dealing with the low hanging fruit to really estimate how many rotten fruit are on the tree is, I mean, we could go around for years and then the other fruit will just start falling off and we'll have some other deaths. We need to attack this particular area now and let some epidemiologists and other folks begin to design the system for incidence and prevalence of this particular disorder.

The costs associated with this, highly misunderstood, not well calculated. There's a research agenda in here that probably would take about half of you in this room 40 years of research to understand this particular area, and that's highly funded NIH research, not the typical \$10,000 small money research. To attack and better understand this, the goings-on in this particular area of the cost of medication errors is quite complex. Not to speak of the various settings, in areas we weren't even thinking about, settings such as not only ambulatory but assisted living settings. Settings where we learned about medication error with schoolchildren and the way meds were passed in the K through 12 system. I learned about the number of folks that are sued in the school systems because they are neglect in the way they pass and distribute medications to our children who are asthmatics, diabetics, and need to have those medications during the school time. Areas that I've not really even investigated or thought about too carefully. And when you start to look at the exclusions, the areas which we did not estimate the costs, you might just say, "Bootman, why did you even take a guess because you're not even—you're just missing the entire picture?" A great deal of research is needed in that area.

We can jump to the general recommendations of the report. They really revolve, as you can see there's some similar pattern to this and the Quality Chasm Report in general. I believe the most important is that provider/patient relationship notion. This is very critical and probably is fruit for your research agenda in the PBRN area. There's better understanding how you will engage patients, consumers, surrogate patients, surrogate others, significant others of those patients, in managing and preventing medication error, whether it's acute care or long-term care or ambulatory care. I just had a son-in-law who was hospitalized and I saw/witnessed medication errors day after day in a very high level facility. And I wondered if I weren't even there to even identify some of it, what would have happened in that situation. And we're talking some very serious, not necessarily due to an individual's fault, but due to the way the system is put forth, the way acute care is handled throughout this country in general.

It's a serious, and the neglect that physicians, pharmacists, and healthcare providers put forth in terms of not understanding the rights of patients and the ability of patients and someone who's in coma. Who's representing that patient to be able to be a part of the decision making on what's happening in that situation? So major cultural changes that are necessary! Increasing the use of technology in the e-world, detection, monitoring. The second bullet very interest—of high interest to von Eschenbach, the FDA

commissioner. They would like to have a better system for releasing drugs for approval earlier than waiting 12 to 13 years, collapsing possibly the Phase II/Phase III if the community world could better handle that product and help monitor and detect adverse events through a system, an organized system of retrieval. I think it's a group like this and a PBRN might be the group of intellect and resources that the FDA might be able to—if you could orchestrate what you're talking about at this meeting. It may serve to lower cost dramatically in the development phase of drug discovery and development.

Oversight, regulation, payment, that was common in the Quality Chasm, and of course there was an enormous, so you know the bottom line, is that last bullet. If you were to form a whole cadre of PBRNs and linkage, interprofessional links, there's probably more research here than it would be a lifetime, three, four, five lifetimes in this room to attack this particular issue. The IOM had—based upon that sixth bullet, our report had so many research recommendations, I mean, there are 150 dissertations, master's theses, small projects that it's just an unbelievable platform of activity.

Now, of course, those of us who spent most of our career in research know that research also is expensive. What I see being funded in the PBRN world to date is extremely minor compared to the billions of dollars that are spent. I am talking hundreds of billions of dollars just to discover drugs, develop them, etc. So to deal with the medication application side of the equation it's going to take potentially billions of dollars to really get our arms around this. That's probably not something that you need to lose a lot of sleep over, because I believe that there are more and more monies and resources that are going to be dedicated to this area. I'll highlight that a little bit in a few moments.

There are many of these recommendations of course we think about over-use, under-use, and as I mentioned, some of the areas that we don't think about all too often, in the psychiatric area, alternative medication use, alternative substance use, schoolchildren as I already highlighted a little bit. Probably the one topic that is concerning more and more CEOs of healthcare systems, and though we have few of those in this country in reality, but the Kaisers and the VAs and the integrated healthcare systems, is this care transition. Medicine has sort of complicated that more so. Lesser of the fact that the typical physician can admit patients to a hospital and follow patient X from ambulatory - and we use more and more of the intensivists in acute care; that's even increased the lack of communications across practitioners in the transition - even across medicine. I hear many of my doc colleagues, certainly in family medicine, etc., complain that the intensivists and Good Sam in Phoenix, they admit and discharge and I can't even get them on the phone to understand what happened to my patient while they were there. That might not be in your particular practice sites, but we see that frequently in the west anyway, in terms of the lack of communication. In pharmacy we've had that problem forever.

Now how many of you are community pharmacy based? And how many calls do you get daily when your patients are discharged from hospital X about what went on with their therapy in that hospital. At Kerr Drug, do you get 100 calls a day in your city? I doubt it. So you just - whatever happens. Oh, Mrs. Jones, you were in the hospital for an appendectomy, etc., etc. I see that they've got you on this. That transition of care is—it's

amazing even with the technology we have that still a phone call is not made. Pharmacist whose in St. Joe's Hospital calling Rebecca Chater and saying, "Hey, one of your patients we just discharged. This is what happened. These are the issues that they were concerned about as we transition them to your practice site." If we were just to attack that particular area in terms of care transition across sites we'd probably make some remarkable—I believe that's a low hanging piece of fruit for sure.

Unresolved issues. As I began to read all of your materials and understanding the PBRN world, which I have to admit, I knew a little bit about the terminology, but in Arizona I had not been a part myself, being a dean, of that type of a network. I knew that Barry Carter had created one. I knew that Virginia, and Dr. Goode and her operations and a few isolated situations, but not having day-to-day experience. But when I began to think about the topic I'm probably over-obsessed with disease management, the drug product, how we're dealing with diabetic medications, etc., from a technology standpoint.

I also, as I look at the research, and think about improving the practice of pharmacy, that's a very process oriented notion. I'm really more interested, me personally, how well are we controlling the diabetic? How well are we impacting hypertension? So should your research agenda be outcome driven from a clinical economic outcome relative to the patient? Or practice process driven? Probably both are necessary, but we certainly don't want to improve a lot of process without understanding the impact on outcome in that. So something to think about.

Should those outcomes be just clinical outcomes or should it include the economic quality of life dimensions simultaneously? I share this from Gene Reeder in his article that made us think more clearly about clinical, economic, humanistic outcomes simultaneously assessed and evaluated, not just an economic outcome in treating diabetes. And then next year we'll look at the clinical outcomes, talking about simultaneous evaluations and assessment.

Should it be practice, disease, or medication error driven? Should we look at—design studies that are around adherence or adverse drug reactions or the incidence of drug interactions, or should it be more of the outcome related or the practice component? Post-market research, that's the notion that von Eschenbach is looking for leadership on how we can better monitor new drug release adverse drug reactions. How can we prevent the situations that we move from 25,000 person exposure to 2 million and we have a higher incidence or an unpredictable set of physiological events that we didn't see in the clinical trial? Who can help us monitor that because this country, we're not going to have anything to dispense, folks, or prescribe if we don't get our arms, it's going to take 15, 18, 20 years we'll have a new drug every few generations as it moves forth. We need to speed up that process, make it more efficient and effective, and better understood by those who participate.

I believe that community pharmacy may be a key to solving and addressing that post-market situation. We're taking, I know, the Critical Path Institute, which was created by the FDA, happens to sit in Tucson, Arizona, headed by Ray Woosley, a MD- PhD. They

are trying to engage the community pharmacy world in this. But I can tell you it's been a tough, tough road. There's a lot of concern, patient privacy, suits, the legal world, the impact of measuring and monitoring adverse events.

Should it be practice focused? I don't mean or technology—I use the word technology, not necessarily computers and things like this, I use technology, the drug, the drug technology. Not all drugs to me are simple, you know, tetracycline type moieties anymore. Some of them are very complex biological products. Our genomics folks across my patio are exploring proteins and notions that are normal in the body, they're turning and turning off and turning on genes that are—I don't know—they're called drugs or what, so I just use the word technology. But they're interventions to slow down disease or cure disease in the most part.

Should the critical pathway, are you talking about that particular topic, the critical pathway going to be addressed by the PBRNs? Are they historically, are they being planned in the pharmacy version of the PBRNs? Across settings I think a lot of the answers are yes, yes, yes, yes. Where do we go from here? So I'm sort of setting you up.

An untapped resource. How many in the room, in all honesty, are familiar with the concept, I'm not playing a game, but just CTSA? So several of you. And how many of you are intricately interwoven in the development of the CTSA at your campus? So I see, I see the doc here is for sure. It is Zerhuni, Dr. Zerhuni's madness, some think he is mad, some think he's way off in the land of thinking about this, some of the traditional researchers, NIH researchers. But Dr. Zerhuni's madness is to address this notion of research in that laboratory, research that's clinically driven, that's not impacting the real world, is not translated, is not applied in a safe and effective way. And he's hoping to drive that. And using the muscle of the "NIH" and I think that's fine because they have a hell of a lot of dollars so they don't think they have enough. Their \$28 billion is something that I would like to tap into in this research arena. Many folks that work with me tap into it to discover drugs and develop, but when it comes to the application, the understanding, it's very lightweight in terms of the \$8 billion we spend to better understand cancer diagnosis, much less to treat.

Now Barry is one example that's tapped into that, but I can tell you, you can count on one hand the number of researchers that deal with what you're thinking about that are receiving NIH funds to attacking this and approaching this particular area. I think Zerhuni's model, the CTSA model, may open this up dramatically. I can tell you that a researcher, not putting on my dean's hat, but a researcher in this particular area of health outcomes, we are the front page of our application at the University of Arizona. Health outcomes is the front page. That's the part that they think will help sell and achieve success.

There will be billions of dollars over time put forth on this effort. Each institution - there will be 60 CTSA's formed in this country, probably one at least one in every state, some states like California who think they are a country in essence will probably three, four, or five CTSA's before it's said and done. I'm sure Chicago, there's more than one institution

in Chicago, who hopes to have a CTSA. I don't know what the politics and so on between the various institutions there, but that's going to be—that we'll wrestle through. But there will probably be about 60 and maybe they keep inching it up. They started with 52 and 58 and 60 and it might end up being 70 or so. But certainly all of you at the, Earlene at the University of Florida, the major universities, they will spearhead a CTSA. Now you might say, "Well, that's only \$6 million a year, that's the average that they're going to fund." The institutions by which these are affiliated will have to ante up maybe four to five times that amount. We're talking an enterprise that could be as large as 15 to 20, 25, 30 million.

I know up the street here, we don't want to talk about Duke versus University of North Carolina because Duke has one, the UNC has yet to receive one. I'm pretty sure that UNC will probably receive one. But Duke has one and I think I understand that Duke anted up about \$100 million in physical plant, in muscle, in resources to assure that the first round, like basketball, they are going to get that CTSA. Rob Califf, who I happen to know, who is on the medication error study, is the principal PI of that CTSA. Rob's a very world renowned clinical researcher, supportive of the pharmacy world. Unfortunately, he doesn't have a pharmacy school at Duke, but hopefully he's partnering, I think I did see in their parlance their application they are partnering with maybe Campbell or some other pharmacy operations.

The CTSA is a very untapped resource and one that you need to be thinking about how you can carve yourself into that world relative to health outcomes because all of that research that puts forth without proper application, the system will have failed. And you've got the head of that camp, Dr. Zerhuni who totally understands that and totally feels the pressure from Congress, who constantly says, "We're spending billions of dollars to diagnose and all these institutes and we're just not getting it done." Now as scientists we can explain why it, well, it takes a lot of time and effort. But the patience is sort of running out in that equation. It's a lot of money, a lot of time and resource, and we want to see some benefit. Even when we do have therapies that do benefit, indeed, they're not applied correctly and we're seeing that chasm as we use that term throughout all of this.

Many other basic questions that we in pharmacy education, those of us around this research paradigm, what does the ideal research team look like? Should this be an inter-professional effort or should pharmacy land just go off and form its own level of PBRNs or do we integrate? I think some of those questions are going to be addressed at this particular conference as we move forward. How patient centered should it be? How well have the medicine PBRNs been in the area of patient centeredness? Have they really accomplished that particular level? What are the cores? The CTSA's that are formed that I referred to will all have cores. Basically that's what NIH will fund. They'll fund biostatisticians and epidemiologists and core units that will help you get that job done. And some of you are affiliated with the academic settings. You'll be able to walk across the street and tap into that. Those of you that are in more of the practice world, you'll need to link with someone in the academic setting who can help open that door and move into that particular arena.

You will—I believe that the applications that have been successful, those that receive very high marks were those that did engage the pharmacy profession, the nursing profession, and other professional educational academic units as a part of their application. Folks use this particular slide at the end of the day, you know, that's sort of what's the bottom line. I think as I started in the first bullet, leadership is probably the most—the motivation, something those of you who really are dedicated and committed to doing something at the end of these two days, who are going to go back and take one more step forward, whether it's calling the head of the CTSA at your institution, whether it's linking with a family medicine department or your local PBRN, or just starting your own or starting something anew. As it was talked about last night, getting your students, those of you who are in positions that can have your students go out and help out with some of this particular transition.

These are the, I think, the general real world pearls that we need to think about. I believe it needs to be inter-professional. I believe that we do need to have some highly qualified clinical researchers associated with this complex PBRN model. I think the Barry Carters of the world and many others of you in the audience can serve in that role to link with day-to-day practitioners, those practitioners who are dedicated and committed to trying to participate in the research paradigm. But the folks that will write—research is expensive. I don't think we should wing this on a few dollars, this particular effort. Some serious thought needs to be garnished and put forth on how we can mobilize the existing resources and tap into this effort. It's more than a million dollar project. This is going to take a billion dollars to solve. We looked at other disease states, as I mentioned, from Alzheimer's, cancer, etc., they spend \$8 billion, \$10 billion a year. That's just federal government money. Nonetheless, what the industry spends.

And some of these topics is one that our industry, PhRMA, which I would not give up, in thinking about how they wrapped into this. A lot of controversy in terms of what are they looking for, how does it help their bottom line, that conflict of interest type component. But I believe it is a resource that can be tapped into that will help mobilize. Everyone, including the CEO of a PhRMA company, of the Walgreen's as I've mentioned before, are interested in assuring value relative to this technology. To me that should be the modus operandi, assuring value of a technology that indeed can impact disease. It can lower cholesterol. It means the right dose, right drug, right amount, to the right patient, at the right time, and they continue to adhere to that medication. And, of course, all of us know as pharmacists there are a lot of patients that don't need the drug. We don't need to give that statin drug or that cholesterol medication to an 82-year-old who was just diagnosed with high cholesterol. They've made it that long, we might want to rethink. We just looked at our database and were surprised in our medication management center of the 25,000 elderly we served in the last 6 months and are at the university, the number of folks that are 80+ years of age on a statin and they just got prescribed that particular medication.

So the four Ps, as I mentioned in there, from Zerhuni, I borrow from his most recent article in January. I truly believe that he is a committed individual if we can get an

appointment with him and explain this concept and how we wrap it in, we might have some other, if you will, local support in Washington around this topic. Both he and von Eschenbach, both I think are committed to this particular area. He put forth this four Ps. We need to better the healthcare research and the basic science research arena. We need to better and reliably predict how and when disease will develop in whom. And when we can predict it, we can then personalize it. Of course you hear in medicine much of the discussion of personalized medicine. You ask 50 deans in medicine they have 50 definitions of what personalized medicine means. But we know what it means in our heart. We know what it means with regard to drug therapy. When you can personalize you may have a chance to preempt and prevent disease in that paradigm. And probably the most important “P” Zerhuni puts forth in his treatise is participation. And it’s not participation just to engage the patient as sort of a consumerism type of activity. His participation he believes is critical to improving the trust of the public with regard to the healthcare system and healthcare interventions. It’s related to trust and assuring and gaining wider trust of the American public in terms of their role and participation to ultimately improving the healthcare system in the United States, which at 15% of GDP, billions of dollars we spend on American healthcare, we’re probably not getting our bang for the buck as we all know. We’re not achieving the types of outcomes we should achieve for the amount of the expenditure compared to any country, compared to any other system, we could do a much, much better job at effectiveness, safety, and efficiency in that particular area.

So I close with that, maybe entertain a couple questions, and then move on. And I’ll be at the program for the rest of the day and tomorrow so I’d be more than happy to dialog and digress on a variety of topics. Thank you.

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