EP.77 - Ron Piervincenzi FINAL

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis, your host for *BioTalk.* And we're kicking off 2021 with one of our neighbors in Montgomery County, which has a very prominent role, but it's taken us three years to get to talk to him. And I don't know why it's taken so long. But we are talking to Dr. Ronald Piervincenzi, who is the CEO of United States Pharmacopeia, also known as USP, and, Ron, welcome to *BioTalk*.

Ron Piervincenzi: Thank you, Rich. It's a pleasure. And you're right, maybe three years was too long. But we share the blame on that one.

Rich Bendis: We'll correct that after this is done and find ways that we can work together now that we're neighbors. So, there's probably a lot of people that have heard of USP, there's probably a lot of people that have not heard of USP.

0:01:00 But before we get into the background of your organization, I think it would be great for the listeners for you to introduce yourself to them, and sort of a little bit about your history, your background, and how you actually evolved into your current position today, Ron.

Ron Piervincenzi: Happy to, Rich. And it's my pleasure to be here, and I look forward to sharing. There's nothing I enjoy more than talking about the institution that is USP. And so, it's my pleasure. Actually, by training, I'm a biomedical engineer. I did my research in protein engineering, so I was really on the medicine side, even during my PhD work. And I began straddling, I always had one foot in science, but I had my other foot in business. And so, from my PhD, I actually became a management consultant at McKinsey and Company, at their office up in New Jersey, in one of the healthcare hubs in the country. And I spent about 12 years there, about half that time as partner in the healthcare practice, working in biotech and pharma, in mostly R&D.

0:02:03 Maybe not exclusively, but mostly, in and around the areas of R&D globally. And in that time, I also began doing volunteer work, leadership work, pro bono work on behalf of the firm in youth mentoring. It's not

particularly relevant to the conversation here today, except that I really got bitten by the mission-driven non-profit bug in the process. And I decided I wanted to combine the two, didn't really think it would happen, and then the opportunity of USP came along. I spent about a year and a half at Biogen Idec up in Boston. But the USP opportunity came along, and I knew it was a once-in-a-lifetime opportunity for me, personally. I seized that moment seven years ago.

Rich Bendis: You were not in the area, so you actually relocated down to this area to take the position?

Ron Piervincenzi: So, in 2014, I moved down. We live in Potomac in Montgomery County.

Rich Bendis: Super. Well, welcome to Montgomery County. We hope you stay for a long time.

Ron Piervincenzi: It's my pleasure.

Rich Bendis: You go by USP now, but originally, it was United States Pharmacopeia.

0:03:03 But people will say, "What the heck does pharmacopeia mean?" So, there's a lot in the industry that might know about it, but there's a lot that don't. So, could you please give a little definition of pharmacopeia?

Ron Piervincenzi: I'll share it in three parts. So, first, what is a pharmacopeia? What is a modern pharmacopeia? Which is something a little different. And then, kind of in the context, what is USP relative to that? I know that sounds complicated, but it's an old word.

Rich Bendis: Yes, it's been around a few hundred years.

Ron Piervincenzi: Couple thousand years, going back to the Roman Empire. And for the most part, although there's some uses of the word pharmacopeia for very odds and ends here and there, but for the bulk of it, its recipes in medicine. It essentially just means the armamentarium of medicine. But for practical use, it's meant, "What is a medicine?" And for most of human history, it was recipes. In the more modern time, over the last 120 years or so, it's come to become not so much the recipe for the medicine, but rather the specifications, the expectations, what it should be.

0:04:07 What it shouldn't be, also, what it shouldn't have in it, what impurities shouldn't be there. What a medicine should be. From the perspective of

pharmacopeia, in 1820, when USP was founded, there were pharmacopeias at the time, but they were very, very local, is the best way to describe it. There were none in the US actually. And in Europe, essentially, there were at the city level. And so, the USP became the first national pharmacopeia in the world, although we didn't have much of a country at that time. But that was a bold ambition that really stuck. And since then, of course, there are other national pharmacopeias in other countries, more recently.

Rich Bendis: And then, basically, you've corrected me on the correct pronunciation, which is most important, pharmacopeia.

Ron Piervincenzi: Actually, that's a disputed topic.

Rich Bendis: Oh, it is?

Ron Piervincenzi: Yeah.

Rich Bendis: It could go either way?

Ron Piervincenzi: It's about 50/50.

Rich Bendis: Okay. Well, then I'm not wrong. I was half right.

0:05:00 So, that's an interesting history to go back in time. So, let's talk about today about where you are. We've heard about the history. Let's talk a little bit about what USP is today, what it's primary mission is, a little bit about the geography, and then you also talked about how you were driven to non-profit missions. And most people don't know, this is a non-profit as well. So, a little more background on USP and where you are today.

Ron Piervincenzi: Because USP has been an institution for such a long time–it wasn't that we were sort of formed. We were truly formed in 1820, and have been in constant and continuous operation since. And our mission is not different. It's certainly more complicated, but it's the same. And the mission in 1820 was to ensure uniform and high quality medicines across the United States. Really, the only change there has been that we've become global in our scope. We also still include, of course, the US. In the early days of USP, just to ground it in a sort of fun reality, it was founded by 11 physicians, multiple of whom were federal officials.

0:06:05 So, two House members, a former senator, a current senator, as physicians. And then, there were more scientific positions as well. They banded together, knowing that they needed to have some clout behind this enterprise because it would only be as useful as people took it to be. The founding of USP was on January 1, 1820. So, our 201st birthday was a couple days ago. And the signing in the senate chamber was for pomp and circumstance, to make a declaration that this mattered. Because there was no rule of law at the time when it came to pharmaceutical preparations. Pharmacists got involved over time, industry grew up, in the late 1800s, became a thing, and in the early 1900s, became the dominant force for the creation of medicine. And that was the time when it switched over from USP describing what a medicine should be to USP describing the tests, the analyses that you would do to ensure the medicine is what it was supposed to be. And all medicine, all prescription and over-the-counter medicines in the United States, by law, have to follow USP standards.

0:07:05 So, you can't call yourself Acetaminophen on a shelf unless you meet all the USP tests. It's the thing that you never probably thought about, but you realize, of course, must be true because there's 20 different kinds of Acetaminophen, and you can buy whatever kind you want, and it'll work the same way.

Rich Bendis: What do you mean by test? Can you explain tests?

Ron Piervincenzi: They've evolved. There were tests even back as long as the 1800s. They were simple. Some of them were effective. They are ways to analyze the chemical structure of the product, the physical parameters, i.e. if it's a pill, it has to dissolve. It doesn't dissolve, it doesn't work. There are tests for what shouldn't be there, for example. Impurities that are common given that kind of medication that should only be there in either low amounts or not at all. And all these tests together create what we call a monograph. And inside that monograph, you follow those tests. And if you meet those specifications, you can call the medicine Acetaminophen, to stay with the same example.

0:08:00 If you don't meet those tests, it is illegal to call it Acetaminophen. And, lastly, if you call it Acetaminophen, and you don't meet the tests, that's also illegal. So, it's both ways.

Rich Bendis: If it doesn't qualify and doesn't meet the test, can they still sell it?

Ron Piervincenzi: Well, technically, yes, although it essentially never happens. So, you can't call it Acetaminophen. You can label it, you can indicate that it doesn't meet the USP, but no pharmacy would cover that, so nobody does. It doesn't happen.

Rich Bendis: Got you. That means you must do a lot of testing throughout the year with existing and new drugs that are coming into the marketplace.

Ron Piervincenzi: We do. And there's two facets here. On the one facet, we have thousands of these standards. So there are a couple of thousand medicines. Medicines come in different forms. So we have over 6,000 different standards. It's an enormous amount of these standards. The vast, vast majority, the millions and millions of tests around the world, are conducted by industries, companies who make the medicines themselves, to make sure that they're making it to the right specifications, and regulatory authorities, like US FDA and others around the world that are testing the medicine to approve them and to make sure that they meet the tests in the marketplace.

0:09:09 We do have our own labs because we have to create the tests. So, we're not actually testing the medicines, but we are creating the tests and the tools that create these new standards. So, we have our own labs here in the US and some of our other locations, which I can talk about later. In other words, we have to be able to do the tests to make sure that they work. But once we do that, we don't have the role in the enforcement. That's where the US FDA comes into play.

Rich Bendis: I got you. That was my next question. It's a great segue. And we talk about USP and FDA. And so, do the lines get blurred, or is it a very clear delineation as to who's responsible for what?

Ron Piervincenzi: It's clear is the simple answer. And it's rooted in many, many years of history. USP was 100 years old before the FDA was formed. More than 100. And so, what happened, at the point of time in the FDC Act, and the others that followed, were creating the FDA, and in that way, named USP as the official standard. Because it was already in existence and well-trusted.

0:10:05 So at that point, of course, it was created that way specifically to say, "The FDA will us the USP standards," and that's where we have it today. The main purposes, and I think it's important when you think about medicine quality or quality issues in medicine, it's used by the regulator in two ways. One, is when they first approve a medicine, they'll be making sure it meets those tests. So, FDA has their own laboratories and will perform those tests. It's an expectation of FDA reviewers that it meets the USP standard. The second way is in general enforcement. So, in surprise inspections, border tests. Not just the US, but other countries as well, will test medicines against USP standard to make sure that what's coming in is what it says it is. And so, the tests are not any different, but the people performing them, and the reason for the testing is different, both to ensure a quality medicine supply.

Rich Bendis: And then, with all of these tests, you're a non-profit organization, but you still have to support yourself. So, what is your business model and how you support your non-profit organization?

0:11:03

Ron Piervincenzi: It's my other hat, which is, I think, one of the things that drew me to USP. We are a large organization. We have 1,200 staff. We're large compared to what we used to be. We're small compared to a pharma company, of course. But we're large compared to what we used to be, and it's cost a lot of money to maintain thousands of standards. Our budget's about almost $300 million a year now. And to raise that money each year, we have a small percent, about 10%, of which comes in grants, mostly for specialized work. We do global development work with funding from USAID. It's some of the work we're most proud of, but it doesn't write standards. To do most of our work, that 90%, it's revenue from products and services that are the delivery of our standards. For much of our history, we just sold the book. It was literally a book. We don't even have a book anymore. But it was a book, and we had a book, and that was the money that we had. Most of our scientific expertise at the time, and still to this day, is volunteer.

0:12:03 Volunteer scientists. At the time, going back 50 years ago, almost all the laboratory work was done in pharmaceutical companies as donated effort. That wasn't feasible, given volume of work, etc., over time, and USP developed its own labs. Unfortunately, and we had to be scrappy,

but we've been able to have physical products, like physical reference standards, database access, online access, which raises enough money to do our work. And it's going OK. It does give us a lot more independence, which is the plus side to the challenge of raising the money each year.

Rich Bendis: Another standard-setting organization that I'm familiar with is NIST, which is right down the road here in Gaithersburg.

Ron Piervincenzi: That's right.

Rich Bendis: National Institute for Standards and Technology, who's also in the standards business, except that they're primarily federally funded by the US government, even though they do generate some other incremental sources. And I would imagine that's a big difference between what you do versus what a standard-setting organization like a NIST would do, which is really government-subsidized.

0:13:08

Ron Piervincenzi: That is a difference. The biggest differences between NIST and USP are more the level at which standards apply. So, the NIST standards tend to be sort of, like, the top level. They set the broadest guidance.

Rich Bendis: The highest level.

Ron Piervincenzi: Yeah, the highest levels. You can basically describe it that way. We are our own pyramid of standards. We have broader standards that are general in their impact on a broad spectrum. But really, the heart of the USP is the specificity. It's a practical tool that gets right down to an individual medicine. Actually, even to individual ingredients in an individual medicine.

Rich Bendis: Got you.

Ron Piervincenzi: It's slightly different. It's higher volume, smaller standards. If I had to describe it in kind of a crude way.

Rich Bendis: Yeah, I understand. Yeah. Even though I'm not an engineer, I happen to be a fellow with American Society for Mechanical Engineers at one point. So, I understand their business model, and I would imagine theirs is more similar to a USP than what a NIST would be.

0:14:00

Ron Piervincenzi: Yeah, and these are totally different fields, but people have compared the idea of USP to organizations like Underwriters Laboratory. So, creating the standards for what a toaster should be, so it wouldn't be on fire. And then, of course, we have a lot of toasters today. And then, of course, generally speaking, all 120-volt appliances should have shrouded cords, but the specifics of each device also has to be outlined. The same is true for medicine. It's different, but structurally, it's the same.

Rich Bendis: And this started out primarily in the US, but you mentioned it's global now. Talk a little bit about the global evolution and expansion, and the role, as well as where you're positioned globally.

Ron Piervincenzi: One of the things that we're most proud of was in, I would say, starting about 1970s, although we had a translation into Mandarin Chinese going back to 1920, we truly began to spend our time making partnerships in other countries, which continues to this day, where other government regulators adopt USP as their standard.

0:15:06 Often, in its entirety. Sometimes, in pieces. And we're a public standard, and that's great. That just means we can have even more impact. We partnered to do that. Many countries over 60 adopt USP as an official standard in their country, some as one of a few, and others as only USP. And in return, one thing that we try to do as best as we can is be present. So we have presences, literally people, in many of the countries that are some of the biggest users of USP, like China, India, Brazil, Nigeria, Ghana. We have a European office that covers, broadly, Eastern and Western Europe. Southeast Asia and Singapore. In those places, mostly, it's partnership. Our India office is the co-headquarters. Hyderabad and Rockville are co-headquarters for us now. And so, we have about half of our labs in India's site, but we also have a team there that is specific to India. They're called our South Asia team. And there, like every other country, it's about working with both the industry as well as the regulator to bring USP standards to them, make sure they're understood, that they're used.

0:16:08 It's complicated. And so, you can't just dump the standard on them. It's about explaining it, making sure it's used properly. And it's a huge part of what we do, but it also means that billions of people receive medicines now based on USP standards, and it's just absolutely exciting for us.

Rich Bendis: We've been talking about medicines this whole time, but when I looked at your website and your breadth of services that you offer, it was broken down into a few categories: global health, medicines, dietary supplements, and food. So, it's not just medicines, you're involved in other areas as well. Do you want to talk and elaborate a little bit more about those other areas, Ron?

Ron Piervincenzi: If you think about the dimensions, the geographic dimension and then the dimension of the types of health products, I guess is a way to put that. Let me start with foods. Foods is unique. We don't have standards for bananas at all. And I know it sounds silly, but you could have a standard for pesticide content or something, but we don't.

0:17:02 What we do have are standards for food ingredients. So, we take food coloring is a good example. It goes into thousands of different foods. It's actually extra important that they are not adulterated with toxic materials and such. So, we have those standards. They are voluntary. They're not required. But they can be really important, and also, there's a very high overlap between the food industry and the drug industry, meaning the same ingredients are being used in both. Sugars, and starches, and emulsifiers, colorants. Those are all examples that are present in both. And so, there's a natural way. Coming closer to home, there are categories that are different mostly by regulatory legal reasons, not so much any other way. So, a dietary supplement isn't really different from a medicine from a scientist's perspective physically. It is different in how it acts in the body and how it's regulated by the government. And, therefore, our standards are similar. We use the same tools and techniques, but we reach people differently. They're not required by law to use USP standards for dietary supplements, for example, in the US.

0:18:04 To encourage them to use those standards, we have something we call the verification program, which, for most Americans, is the only place they see the USP is on the vitamin bottle because it's very prominent. On the front of the label, several companies, some very large ones, have us verify. It's where we actually do the testing that the FDA does for prescription drugs or over-the-counter medicines. We do the testing, and then if they pass, obviously, they can then have a label on there to say, "This meets USP standards," that they don't have to meet, but now, these are companies that choose to meet them. Someday, perhaps, it'll be

regulated by the FDA, and we won't need that anymore. But in the meantime, it acts as a bridge to bring people an assurance of quality for their dietary supplements. And I know most of ours are USP-verified are vitamins. I know for a fact that 100% of my mother's are. In fact, when she learned all this, she threw away all her other vitamins, and only bought USP-verified.

Rich Bendis: That didn't have USP on it.

Ron Piervincenzi: I think that goes a little further than I would encourage for most people, but she's my mother.

0:19:03

Rich Bendis: Probably you encouraged her to get rid of all of the out-of-date foods, too, that were in the refrigerator at the same time.

Ron Piervincenzi: That's true. No, I did not win that battle.

Rich Bendis: "No, it's still good." And so because of the proximity of the USP and FDA being so close together here, and even though the geographical proximity isn't that important these days, is there much communication you have with the FDA since you're trying to work on similar standards, but from a different perspective?

Ron Piervincenzi: It actually is important. And in fact, they used to be on the same street as we did until the FDA moved to White Oak about ten years ago or so. They were literally on our street, so you could walk across the street and down the street. And that's why we had set up our office there. I will come back to that answer, but how'd we end up here? Up until 1950, USP was sort of headquartered in New York, on Park Avenue, actually. There wasn't much there because most of the work was done in a network sense. But our first staff member was our first CEO in 1950. Moved down to Bethesda for a short time, and then Rockville to be near the FDA.

0:20:02 And it was an important decision. Right now, we have 26 expert committees to cover this broad area, including food supplements, all the types of medicines, both oral medicines, biologics, injectables, this full spectrum. We have 26 committees, between eight to about fifteen or so scientists each that are non-USP staff. It's hundreds and hundreds of volunteers. They sign up for a five-year term. The chairs are elected, and

it's quite an extensive process. And it's been going on for many, many years.

Rich Bendis: It's unpaid though, right?

Ron Piervincenzi: Yeah, unpaid.

Rich Bendis: Unpaid, but it's prestigious to be on one of these committees.

Ron Piervincenzi: It is, and it's real work. It's ongoing work, not just for a couple of meetings. It's for a five-year period of time, ongoing work throughout. On actually all 26 of those committees is at least one, mostly two FDA what we'll call government liaisons. They only difference is they don't vote, and that's by FDA rules. But otherwise, they're full participants in all the standard-setting work on every committee. More than two. On a few committees, there's three or four.

0:21:03 So, I mention this because not only, of course, do we have ongoing interactions at all levels, but that's a very extensive interaction with hundreds of FDA staff. And so, it's constantly going on. It was easier when they were across the street, but White Oak's only about ten minutes away.

Rich Bendis: Yeah. Well, as economic development, we're also looking for ways to attract and retain people here. I guess having both of you located in Montgomery County doesn't hurt for those people who are actually going to go through those approval processes.

Ron Piervincenzi: Yeah, I think it's a big benefit. I think it's one that the region hasn't fully take advantage of yet, but there's still opportunity and I've spoken with Mark Erich and others about this is the deepest wealth of medicine and regulatory talent in the world in one place. For sure. There isn't even second place. Not even sure what it would be. And yet, it's almost ignored because the impact is global. Same with USP. Most people don't even know the organization's here. But it does matter. And we've got 800 staff, FDA has several thousand.

0:22:01 It's a significant portion of the health population. And that's not even mentioning NIH as you branch a little bit further, and NIST, for example.

Rich Bendis: Yeah, I was just going to mention NIH. But, well, you now have Rich Bendis, who's going to be one of your promoters, too, Ron.

Ron Piervincenzi: Excellent.

Rich Bendis: And we really have not taken advantage of that. And because I always talk about the unique assets that exist in what we call the BioHealth Capital Region that can't be replicated anywhere else in the world.

Ron Piervincenzi: Correct.

Rich Bendis: And so, at the end of the day, there's only one NIH, there's only one FDA, there's only one NIST, but there's only one USP. And to have all of those headquarters here–and you've been discounted because I have not included you, nor have many other people included USP in that category of unique assets, which we need to start branding it more effectively. So, we're going to talk after this podcast about ways that we can get you more included, and we should recognize better what you're offering globally and the advantages it has to our region for your presence being here.

0:23:01

Ron Piervincenzi: That's great. I look forward to that, Rich.

Rich Bendis: For sure. So, we've talked about the benefits of sort of being here close to the proximity of the FDA and the other resources here. What about proximity to companies? Is there any benefit for you to have GSK, or an AstraZeneca, or an Emergent in your backyard, or United Therapeutics, or MacroGenics, or some of these new developmental companies right here for you to work with as well?

Ron Piervincenzi: Yes, there is. In fact, the footprint we have around the world is intentional that we have people close to the partners that we work with. I mentioned there are hundreds of volunteers. About 65% of those volunteers are in industry. That's where they are. Now, of course, there were also academics, scientists, and regulatory science experts from governments as well. But most are in industry. That's where most of the scientists are, in the pharmaceutical space. So, being close to where those companies are is really helpful.

0:24:00 At the same time, it's a networking opportunity that we've all learned this year that you can also work more effectively than we would have realized more remotely. I will say, from our perspective, we don't want to ever

experience 2020 again. I'll put it that way. But we did learn some things that will help us be effective, both with that connection locally and to extend it globally, to the advantage of everyone, including those that are local. Meaning to be able to pull those other individuals in closer together.

Rich Bendis: And, really, let's talk a little bit about the implications of the pandemic and the Coronavirus. You talk about global health, medicines, dietary supplements, and food. So, we're looking at vaccines, we're looking at therapeutics, we're looking at diagnostics. So, what has USP's role been related to this whole pandemic and the interaction you've had in any of those areas?

Ron Piervincenzi: Going back to, let's say, about April, a few weeks after we went remote for our office staff, our non-essential, mostly non-laboratory staff. Like everybody else.

Rich Bendis: Like you and me.

0:25:01

Ron Piervincenzi: Like us, yeah. In fact, I spent the first two weeks going to the office, and then I got a letter from my general counsel that said, "Ron, we love you, but we don't need you in the office, so stay home."

Rich Bendis: I understand.

Ron Piervincenzi: And I said, "OK." They let me go in once a month or so just to say hi.

Rich Bendis: To see if it's still there.

Ron Piervincenzi: But I'll answer the question. The point being, to protect the staff that need to be there. No one complained. Everyone got it right away when we went remote. We have about 120, 130 or so in Montgomery County. We have an office in Frederick as well, where we have about 100 people total with a lot of laboratory and logistics work. And those staff have to work. They can't work from home. And so, to protect them, we want everybody else out. So there's fewer people in the building and all of that. So, when we sat down, we said, "Look, we're going to do two things, and it's going to become our focus for the year." The first was, I would call, the broader impacts, what we call supply chain of quality medicine.

And I'll come back to it, but the pandemic had indirect and direct hits on the medicine supply chain.

0:26:03 And USP standards play a really important role in ensuring the continuity of medicines. And I'm not just talking about the medicines that were, let's say, being spiked use during COVID itself like Remdesivir. Including those, but importantly, they were medicines having nothing to do with the pandemic that were getting hurt by shortages, national behaviors, shutdown of flights was causing medicine shortages. The second work stream was maybe more intuitive, more obvious, which is COVID vaccines and therapeutics. So, our standards are used in those medicines, like others. And so, we made special task forces to meet every need as possible so that the USP standard or access to us is never a barrier to slowing down a new therapy or a vaccine. So, that's been definitely a very important part of our work. It's not been as large as the first one on the supply chain because that one is so much - it's complicated, and it's not an only COVID challenge.

Rich Bendis: Well, they could use you more in the supply chain right now, I think, globally and nationally, as we're having a little challenge.

0:27:02 But, for example, when we talk about Pfizer and Moderna's new vaccines, which are actually being injected as we speak…

Ron Piervincenzi: And NovaVax, not too far behind.

Rich Bendis: NovaVax and AstraZeneca right behind. And then we have Emergent that's going to be manufacturing a lot of these. So, I look at our region as really one of the epicenters in helping to address this global pandemic. The GSK's global vaccine headquarters, primarily, for their research is going on in Rockville. And AstraZeneca with Oxford. And what I've really liked with the proximity, and we talk about this BioHealth Capital Region, is people who have competed with one another are now collaborating with one another because they know how interdependent they are on each other to become successful in addressing this pandemic.

Ron Piervincenzi: It's actually really true. For people who have worked in industry a long time, it's not as surprising. People on the outside are really surprised by it. My impression of the pharmaceutical industry, why it's so different than others in terms of competitive behaviors is that there are thousands of medicines, and each company has its own portfolio.

0:28:08 But their portfolios are all different. So, one is injectable oncology and cardiovascular. Somebody else is doing endocrine and rheumatoid arthritis. Etc., etc. And when you put them all together, probably everyone competes with somebody on something. But nobody competes with everything with someone else. And therefore, while each medicine is competitive, they're very competitive at an individual drug level. At an overall company level, they kind of compete a little bit with everybody. From my own personal experience, I don't think most companies are like that. Car companies are not like that. They all compete head-to-head all the time. It's different. And I think you see those behaviors where the opportunity to work together is higher. In this case, I think we've seen quite a lot of it. I've been really impressed, honestly. And I'm not in industry. But the speed, the quality of which these vaccines have been founded is unprecedented, and I would say, quite different than the response by many countries, including the US, we've had a terrible response to the pandemic from a public health perspective, but the vaccine production has been absolutely astounding.

0:29:06

Rich Bendis: One of the things to reinforce what we're talking about, how important our region is, is that there's about $16 billion that BARDA was using to help stimulate the companies in addressing this pandemic. And Montgomery County companies received about $8 billion over the last nine months from BARDA as well as DOD and a few other organizations. So, we're talking almost 40% of the BARDA Warp Speed funding has come into one county in the United States, which is Montgomery County, Maryland.

Ron Piervincenzi: And then, you take it further, there's been additional investments that are not quite at the scale but can grow over time in Virginia for manufacturing. And not direct, but this is the indirect side in supply chain to bring more manufacturing onto the US shores. We're starting a partnership down there in Richmond to start more companies and a non-profit that's building this up. So, also BARDA-funded there.

0:30:00 And why is it there? Well, think about it. Why wouldn't you want to be in the region? Why specifically Richmond? I'm actually not sure. It had something to do with the site. But that it's in the DC region, access to FDA. Things are not quite as close, but it is real. And despite the fact that

everything can be virtual, everyone works separately, look what happens with tech. Look at what happens in Boston and San Francisco. The super cities are stronger. It continues to be stronger. So, I think you can't ignore proximity as one of the drivers.

Rich Bendis: I had one of the major developers up in Boston who started referring to our region as the next Silicon Valley, but in the BioHealth space. And that's not a bad reference to have these days. As for people who don't know much about the region to understand that we have for people to be attracted to and take advantage of from a networking perspective.

Ron Piervincenzi: One way to think of it, Rich, is the DMV. I don't use that term. I read it all the time, but I don't usually say it. It sounds sort of…

Rich Bendis: It's BHCR. BioHealth Capital Region.

Ron Piervincenzi: Ah, I like that better. I like the BHCR.

0:31:00 Pulls in Baltimore. No, I like that better. So, the BHCR region, one of the reasons I think it hasn't been recognized is one of its strengths, which is the diversity. So, it's got some medical device, the vaccines, it has some traditional medicines, it has the government agencies, it's got the non-profits, the USP.

Rich Bendis: Research universities.

Ron Piervincenzi: Yeah. There's some fantastic universities. Hopkins might be the best medical school in the world. But because it's so diverse, I think it's not been obvious. It's not been tagged obviously. And when you look at the future of medicine, this is kind of where I'm getting to, everything is becoming joint. There's very few pure plays anymore. Something like 60% of the new drug pipeline are in combination with some kind of medical device or software. And you play that forward, personalized medicine with a combination of sort of on-site care with industrialized production. What we've got going here, I think, is for the future. So, I think the future actually is really bright. Not that it can be ignored, but it's set up, I think, really well.

Rich Bendis: And I think your explanation's very well.

0:32:00 And that's why we use the term BioHealth rather than biotech or life sciences.

Ron Piervincenzi: Yeah. Good. I like that.

Rich Bendis: Because you have the convergence of technology, diagnostics, medical devices, therapeutics, biosimilars, as you've mentioned, artificial intelligence, quantum computing. And everybody's becoming interdependent not his, whether it's a healthcare provider, whether it's a pharma company, whether it's somebody in the medical device or diagnostic field. And as you've mentioned, we have some of all of that within our region, which is unique to our region.

Ron Piervincenzi: And I'll mention one other, Rich, that, at least for USP is really important is DC. So, the power of the government is clear. Because of that, virtually all of the health organizations are headquartered in DC. So, all the pharmacy associations. AMA is not, the American Medical Association. They're one of the only who are not in DC. But all the pharmacy associations, the heads of the industry, bio, pharma, they're all in DC. They're on the red line. I mean, literally.

0:33:00 That's a huge advantage for USP because they're our convention members. They're our governing body. I'll go into details there, but that's who owns USP are our convention members. But that's not just true for us. So, if you want to be with the influencers, but also the technology, it's how you get to have both. And then, you throw in FDA, NIH, NIST, USP. As I say, it's not that it's unique, but it's kind of unprecedented. There is no place else in the world even close to that.

Rich Bendis: It is unique. And we're going to have to do an advertorial for the BioHealth Capital Region with you, Ron, and you can be the star.

Ron Piervincenzi: I don't mind that. I really get a kick out of it. I didn't mention this before, but when I was in college, I had a really great opportunity, which in truth, probably launched my career, where I did two summers of research at the Naval Research Lab in southeast DC down by the river. And I got a little bit of a flavor of the region and some of what was here. I was a very naive kid. But I saw a little bit of things that people didn't know about in DC, and that there are labs in the Army, Navy has labs, these are all here, too.

0:34:01 And they're not huge today or maybe the most important, but there's a reason that this other stuff is here. And it started going back further in

some of these more specified areas, like BA and the NIH hospital. That's how these things started.

Rich Bendis: We're talking with Ron Piervincenzi, the CEO of USP. And before we wrap up, Ron, is there anything that you'd like the listeners to know about US, your future, where you see 2021 and beyond going, that you'd like to enlighten us about?

Ron Piervincenzi: I'll kind of share what we have as a couple of our priorities for the next year. It's a two-pronged approach. On the one hand, we've got to take care of the basics. We learned with toilet paper and medicines that the bottom can fall out. Toilet paper, you know, is a joke. But in medicines, it's not a joke.

Rich Bendis: It's not a joke, really.

Ron Piervincenzi: The medicine shortages this year have been quite serious. And what you can take for granted, that, "Well, somebody will make it," or, "It'll be there," we've kind of learned isn't always true. Not if you don't take care.

0:35:00 So, one area there is, "How do we build resiliency?" That's the word we use. Which doesn't mean perfect. It doesn't mean you can prepare for everything. But you've got to beef things up to be better prepared. The resiliency in our medicine supply, especially for generic medicines that often fall through the cracks, and especially-especially for the simplest, cheapest generic medicines that are the ones that are most often ending up in shortage. And the other is actually the opposite end, innovation on the front end. And to not only bring it quicker, and also to ensure that the quality is there at the beginning, not after the fact. So, in areas of personalized medicine, drug device combinations. You mentioned earlier about the diagnostics. I should've mentioned that. That's one of the big advantages of the region. The combination of diagnostics with medicines are all great opportunities, but they're also more things that can go wrong. And ensuring that the expectations and standards are set early helps get things approved more quickly. We've actually measured this. It helps companies get out there more quickly. It lets people build on a higher level.

0:36:00 Rather than starting from the ground every time, they can start with the basics in place. And so, what's unique? How is it different? Wherever you stand in history, the next ten years, new things happen. And in medicine,

though, we're at kind of an explosion. And maybe this is a good way to wrap it up. But we're sitting at a point where we've had you look over the last several decades. A new modality is a term we often use. Kind of a new kind of medicine. From a pill to a biologic. From a biologic to an engineered biotherapy. But we're on the cusp of four or five at the same time. Gene therapy, cell therapy, the special drug device combinations that have advanced. Every one of these is a completely new kind of medicine with entirely new rules, different ways to reach patients, different supply chains. And they're all happening right now. Not the future. But they're actually approved now. Gene therapy is real, cell therapy is real, the combinations are real. Digital medicine three years ago was the future. Now, there are a dozen approved by the FDA. Every one of those is completely new, and they're all happening at one time.

0:37:00 I think that's absolutely fascinating. And maybe we're going to get out of the doldrums we've been in for the last decade or two and have the new surge in innovation, at least in healthcare.

Rich Bendis: And really, if you look at the bio and the pharma industries, they're some of the most innovative in the world of any industries. And we're lucky, you and I, to both be participating in these industries daily. And to be honest with you, I feel sorry for those businesses that are suffering through this pandemic and through COVID, but if you look at our region, we have been a little more fortunate because of the amount of people that are actually trying to address positively some of these therapeutics and diagnostics, the vaccines that are going to affect people globally. So, I feel good about the industry that we're in today and the difference that it's making, where sometimes it's been underappreciated. They get focused on pricing issues, then they don't talk too much about the innovation and the improvements in the quality of health that people are trying to do with the companies that we work with on a day-to-day basis.

0:38:03

Ron Piervincenzi: That's well-put, Rich.

Rich Bendis: I want to close by thanking Ron Piervincenzi, the CEO of USP, located in Rockville, Maryland in the center of the BioHealth Capital Region and, really, the epicenter for BioHealth in the world. And I learned a lot more about USP today by talking with you, Ron. I want to continue this

discussion after the podcast. I think there's many more things we can do together, but more importantly, the work that you're doing is so important to people around the world, we need to make more people aware of the work you're doing and the benefits it has to mankind.

Ron Piervincenzi: Thank you so much, Rich. It's been a pleasure, and I do wish everyone to be safe, stay well, and hang in there for a few more months. Let's let the vaccine do its job before we all get out there and reemerge from our cocoons.

Rich Bendis: Happy New Year, and good health to everybody. So, Ron, thank you very much for being on *BioTalk*.

Ron Piervincenzi: Thank you.

0:39:00

Narrator: Thanks for listening to *BioTalk* with Rich Bendis.

End of recording