Barbara Lopez Kunz – CEO, Drug Information Association (DIA), USA

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Barbara Lopez Kunz, CEO of the Drug Information Association (DIA) in the USA, outlines the association's four key areas of focus – regulatory science, patient engagement, translational science, and value and access – and highlights how it works with stakeholders across the healthcare continuum and across the globe.

What is the mission of the DIA?

DIA's mission is to improve the health of people worldwide. We do this by bringing together thought leaders from across the global healthcare stakeholder community to collaborate on topics that accelerate the delivery of therapies to patients. We generate and share knowledge to advance therapies – and the careers of healthcare professionals – globally.

We focus on four core areas of the healthcare continuum:

Regulatory science. This has been at the heart of DIA from its founding in 1964, which was based on the need for better collaboration to inform improved regulatory and clinical decisions. DIA fosters conversations between regulatory agencies, industry, and patients around the world, working to increase efficiency through regulatory convergence.

Patient engagement. Thanks to our visionary Board of Directors, DIA has for more than 15 years embraced the importance of patients being engaged in their healthcare and partnering in the development of therapies to meet their needs. DIA has been very involved not only in convening and sharing evolving knowledge on this topic, but also in conducting research to advance the thinking in this area. We are using our global platform to disseminate learning worldwide as the recognition of patient engagement has risen in priority across the entire healthcare community.

Translational science. Our focus on the evolving clinical enterprise includes everything from discovery through to clinical research and development, licensure, and post-licensure surveillance. We are shepherding innovations to accelerate trial design and conduct and furthering the use and trust of new technological paradigms, such as AI/ML, to address opportunities for better patient outcomes.

Value and access. It is important that all people within healthcare and, importantly, those who benefit from the advancements in the field, understand the value of innovation and how that translates into new treatments and cures. We are in discussions around the sustainability of healthcare, what kind of evidence could support value assessment, and we are helping to enhance the narrative on the importance of biomedical investment and innovation. Of course, those innovations need to be made accessible to patients who need them.

If you look across the healthcare continuum, there really is no other neutral, global, interdisciplinary organization that covers the breadth of science, technology, and policy – whether it is drugs, devices, diagnostics, or digital – across the entire world, like we do.

I believe that many of the most challenging issues in healthcare exist at the system level, and this is what enticed me to join DIA. The regulators, industry, patient groups, and payers can self-optimize but, frequently, the critical challenges exist at the interfaces between these groups. We identify the system-level topics that are uniquely global and cross-disciplinary and will benefit from engagement on our neutral platform. Our goal is to bring forth the best thinking and expertise to tackle difficult topics, create solutions that will help our community learn and advance, and move forward the science and ultimately, health policy.

One of the main advantages of being based in the USA is the fact that the FDA has historically been the gold standard for regulatory science. Is this still the case?

The FDA has a long track record of making significant advances in regulatory science and has set the stage in many areas of regulation. However, the FDA is not alone; the European regulator network, for example, is finalising their Regulatory Science Strategy, and other regions are creating regulatory frameworks and improving processes in certain areas that will become the gold standard in their own way – because there is a certain level of agility that comes when you are starting fresh. We are cognizant of this, and we make sure that best practices and educational content from both developed and emerging regulatory agencies are shared with our community.

DIA is also active with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). We are an ICH authorized Training Partner and, over the past several years, have provided several training programs on ICH Guidelines for industry and regulatory authorities so that they can participate at a global level.

The USA is always going to be a critical player in global regulatory science. While topics such as expedited pathways, novel clinical trial designs, and guidance for patient engagement in healthcare are being advanced in many places around the world, the US FDA plays an important leadership role. It is very beneficial for DIA to act as a resource for FDA and its leaders to help them disseminate their work in these areas and facilitate their engagement with industry and other global regulators.

We also work very closely with the European regulators. We have a long-standing partnership with the European Medicines Agency (EMA) and support the various National Competent Authorities (NCAs). We have a strong relationship with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan as well. These three founders of ICH have helped DIA form our Council of Regulators, an open network of regulatory leaders who provide guidance to support DIA's strategy, ensuring we use our platform to advance regulatory science and policy.

In Asia, China has done an amazing job in moving regulatory policy forward, and the National Medical Products Administration (NMPA) has been quick to build its capacity and capabilities in hiring and educating staff to be able to make sound regulatory decisions. We were involved with supporting China to join the ICH at the end of 2017.

Within the ICH framework, the European regulators, PMDA and FDA are working towards reciprocal alignment, whereas countries such as China may wish to simply take this as the golden rule and apply it at home. But reciprocity should go both ways; do you see this coming? What might be the reaction of the regulatory community if this

reciprocity is asked for?

I believe that this reciprocity is coming. Right now, however, the NMPA is focused on establishing their own capability and getting products that have not previously been available, approved for Chinese citizens.

Also, there are so many new therapies emerging in China. They have their hands full trying to service local needs. So, we must be a little patient and allow them to establish a level of operability where reciprocity can become possible.

I am optimistic. I have witnessed the investment of significant energy and time in advancing R&D and regulatory science in China. Unless proven otherwise, I trust that they will get to a point where reciprocity becomes a mutually beneficial activity.

DIA is not a government organization but has been granted the trust of regulators, which must have been a delicate balance to strike. How do you lead and work together? And how do you keep this balance to ensure that there is no disruption?

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Striking this balance is a top priority for me and for our Board. DIA was founded on the concept of serving as a neutral trusted platform, and and this is not only discussed but underscored at every Board meeting. We have many opportunities that must be evaluated against this philosophy. We ensure that DIA is not influenced in any way by any particular segment of the broad global healthcare system – our top priority is to stimulate and share the best thinking and top insights.

It is so important that we maintain that philosophy to put forward thought leadership. We encourage divergent points of view as it is in these discussions and debates that new insights emerge. We don’t adjust or massage our members and volunteers’ contributions. We recognize that learning is a continuous process, and we want to share the various points of view so that the life sciences community learns as a whole. We find that the regulatory community appreciates that what we share – perspectives, findings, and policies – is reflected in a neutral and trusted way.

Another thing that differentiates DIA is that, as an individual membership organization, we do not lobby or advocate for particular policies or perspectives. People participate in DIA as experts in their fields, personally dedicated to advancing healthcare and life sciences. We do not accept

funding from any organization, whether government, industry or non-profit. Most organizations encourage their staff to invest in educational activities and see DIA as an excellent resource. Individuals see DIA as their professional society, the place where they meet with others and network, learn, and share. There is certainly a mission-driven sociology within DIA – people who feel a connection with the DIA mission and a personal mandate to work together to advance the field and bring life-saving therapies to patients.

Finally, we have led cross-collaborative research projects on topics of interest across the drug development ecosystem, and these projects are open to anyone that wishes to participate. From these projects, we have generated a substantial level of new findings, which are shared on our various platforms – conferences, publications, and educational tools. And, over the past few years and at our members' request, we launched a new online tool called DIA NOW, where the knowledge shared by our members, faculty, and speakers is captured and provided as resource for the latest trends and up-to-the-minute updates on a wide variety of critical issues in the life sciences arena. We have had a tremendous response to this initiative, because it allows our community to access knowledge conveniently – in-person, as a group, in the quiet of one's office, or on a mobile device.

As a leader, how do you ensure that all voices are heard in these meetings, as the participants come from markets with vastly different levels of regulatory complexity? It must be intimidating for some.

It is true that the regulatory systems are not yet harmonized globally but they all strive towards the same goal as DIA: safe treatments for patients. Some countries, like the US, Korea or China have a single regulator, while others, for example, Europe, Middle East and even Africa in the future operate as a regulatory agency network. All our meetings are designed by volunteer experts, tailored to the needs in the country or region. We have thousands of volunteers around the world who serve the community by helping to shape DIA events. For example, if we are having a discussion around what is happening in China, Korea, or Japan, we engage with experts in chosen fields, as much of what is covered at DIA either is of global interest or should be. It is through outreach efforts within our global network that we have been able to expand our reach in Latin America, Africa, and the Middle East, establishing new relationships, partnership and meetings. To facilitate the participation of newcomers, we offer pre-conference training courses, aligned to the content of the meeting, to ensure attendees are ready to engage at the appropriate level. We also provide simultaneous translation, so that exchange can happen between people who speak different languages.

We ensure that, in our meetings, topics are being advanced. Our audiences appreciate the dialogue and debate – our speakers are not only reporting out. We encourage people to share different perspectives in open dialogue and on our respectful platform. Our job is to capture the debate and share it. We see that successive discussions generate new insights, and we have the channels to continuously share these to benefit the community's learning and awareness.

Our pinnacle event happens annually in June, at DIA's global annual meeting, this year in Washington DC. We will have attendees from 70 countries, and the program is designed by an international steering committee and program committee, all of whom volunteer their time and expertise to create an event that attracts thousands of participants. The program committee designs our themes and decides which topics are timely and critical to cover. We do an open call for abstracts and can accept only 15-20 percent of the proposals we receive. We also work to capture all the knowledge generated in our publications, and on DIA NOW, so that it lives on and can be shared globally afterwards.

Today, there is a lot of distraction from the fundamentals, especially in the area of regulatory science, with data, AI, and real-world evidence. What role does that have in the DIA? Do you sense this as a distraction?

I see these evolving fields as a huge opportunity. We are living in a time of incredible advances in science and technology, and we have seen the positive impact in many ways in healthcare. New therapies, new diagnostics, and cures are available today that we never imagined possible. Our health innovation ecosystem is alive and well and is impacting regulatory policy, academic institutions, industry, and patients.

When I was a young girl, getting a cancer diagnosis was a death sentence. That is no longer the case. There are tens of millions of people around the world living as survivors of cancer. That never would have happened without the kind of investment in new science and technologies, such as genetic testing, immunotherapies, and countless treatments available to patients today.

Advances are being made with the integration and use of data, and tools are available that accelerate insights – such as in clinical research – support regulatory decision-making and increase efficiencies and effectiveness of processes. People ask – why does it take so long and cost so much to develop a new therapy? These new approaches may provide ways to accelerate our processes and reduce risk, with the potential to lower costs.

We are finding ways of using AI and machine learning tools to generate new levels of understanding. Over time, processes are shifting, and we have faster, more accurate means for making decisions. We know how to integrate real-world data from research methods and from physician care to find new indications and methodologies. I am a researcher, and I want to help figure out how all these new approaches can be beneficial for patients.

DIA has published work assessing the use of AI across drug development, led by several different organizations. We see that there are many places where AI is being used in drug development, and there are more emerging. We are sharing what we learn at our meetings and in our publications, while we are also exploring new topics. It takes organizations like DIA to share learning in non-competitive interactions.

What is your stance on the Googles of this world coming into the highly regulated and data-sensitive healthcare market with large pockets of cash and previous experience only in largely unregulated industries?

We welcome it. At our annual meeting, companies such as IBM Watson, Microsoft, and Google are present, sharing their findings and learning from the broad community. They are developing new technologies and new ideas that will benefit patients. These organizations know that they must work within the evolving regulatory infrastructure to get safe and effective treatments to patients. The ideas they are developing must be done in collaboration with the regulatory community, which, on its own is continuing to evolve to apply new thinking and practices. As new technologies that do not fit conventional regulatory frameworks, such as CAR-T or gene editing, are being evaluated for their benefit-risk profile or new manufacturing techniques, regulatory processes will need to evolve with them. We will see this continue as new players enter the health arena with novel and effective products.

What is rewarding about working in healthcare is that there is tremendous opportunity for improvement, there is so much dynamism and evolution, while at the same time the true thing that people aim for is to do what is right for patients, to make cures and therapies available to patients, wherever they are in the world, when they need them. All of that is moving in a direction that is very positive for the future.

DIA is also working on value and access. Why is this important to the association and how are you pushing this concept forward?

Our advisors encouraged us to bring this part of drug development into DIA, as it is key to include the thinking early in the process. No one wants to develop a product that is not accessible to patients. We are bringing the whole system together at DIA, and we believe the experts involved in assessing the value of an innovative treatment must be part of the dialogue. We care about how to ensure therapies are accessible to people and how to develop an understandable narrative on the value of therapeutic innovation. There are ethical issues at play, and we have the thought leaders who are advancing knowledge in these important areas.

As part of DIA's strategic planning, we listen intently to our Science and Policy Advisory Council. This council, comprised of experts in healthcare product development, advises DIA on emerging science and policy issues and trends globally. You will see us evolve as we learn about how DIA can be supportive beyond the various discussions and publications we have generated on these topics.

What is your message to our broad, international audience?

We stand at the precipice of healthcare looking out on the possibilities of extraordinary therapies and cures. To bring them to fruition, we must face complex, global, and interconnected challenges. The remarkable convergence of science, technology, and policy makes this a critical time of focus. DIA is a truly unique organization that is leading the way to a brighter future in healthcare. I invite everyone with a passion to make a difference, whether you are a student or a seasoned professional, to join us.

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We bring together the global multi-stakeholder community with the goal of addressing the critical challenges we face to deliver medicines to patients when they need them – the overarching mission for all of us dedicated to health. Participate in the conversations, learn from the people who are driving the discussion, and be a part of the solution! We welcome anyone who wants to join a dedicated community working to benefit patients around the world.

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