



## LEADERSHIP PERSPECTIVES

### LEADERSHIP IN MEDICAL SAFETY & PHARMACOVIGILANCE

*Installment #10 of a multi-part series*



**JOHN PRACYK, MD, PHD, MBA**

In this special edition of our Leadership Perspective's series, MAPS Americas Region President, **John Pracyk, MD, PhD, MBA** speaks with the three Medical Safety, Chief Medical Officers from Johnson & Johnson representing Janssen Pharmaceutical Companies, The Consumer Group of Companies, and Medical Devices & External Innovation. At the time of these interviews John served as the Integrated Leader of Medical Affairs, Preclinical and Clinical Research at DePuy Synthes Spine of Johnson & Johnson Medical Devices. Rather than publishing each interview separately, John has chosen to organize these three Medical Safety, Chief Medical Officer interviews by topic, distilling the opinions of three thought leaders to demonstrate consensus or offer distinct viewpoints on issues of importance for the practice of Medical Safety.

The process of conducting these interviews marks an inflection point in Dr. Pracyk's own career. Within 6 months of completing this exploration into Medical Safety & Pharmacovigilance John transitioned from a Medical Affairs role to become the Chief Medical Safety Officer, SVP for the Olympus Corporation. How did these leaders make their way to Medical Safety & Pharmacovigilance? The routes into Medical Safety are as diverse as the medical professionals that it attracts, with many arriving from different settings including academia, strategic consulting firms, hospitals, health systems and real-world clinical practice. However, one constant remains true, they are extremely committed to being an independent voice that amplifies their organization's commitment to Patient Centricity.

**Question 1: What is your personal background prior to entering Medical Safety and how did you transition to a nonclinical career?**





## Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

St. Johns Medical College, MD (MBBS), Medicine & Surgery

Joseph L Mailman School of Public Health, Columbia University, MPH

- Primary care physician, India
- Through that experience my passion quickly became population health
- Moved to New York City to pursue a Master's in Public Health at Columbia
- Management consulting work involving strategies for the payers soon followed
- A medical director position at Pfizer health solutions resulted
- By delivering disease management, it was closer to population-based health
- I transitioned to lead medical communications, external medical affairs, and quality at Pfizer
- I joined Johnson & Johnson as CMO in Medical Affairs of the Consumer Group of Companies
- Currently, I am the Vice President, Chief Medical Officer (Medical Safety) of Medical Devices and Global External Innovation





## Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

Binghamton University, BA German Language and Literature

State University of New York, Downstate Medical Center, MD

New York Bellevue Hospital Center, Emergency Medicine Residency

University of Colorado, Rocky Mountain Poison & Drug Center,  
Medical Toxicology Fellowship

- Director of Emergency Services, Emergency Physicians at Porter Hospital, Denver, CO
- Vice President, Medical Affairs & Clinical Research, McNeil Consumer Healthcare
- Vice President, Global Medical Affairs, Clinical Research, Toxicology, Johnson & Johnson, Consumer Group of Companies
- Vice President, EMEA Regulatory Affairs and Global Medical & Clinical Affairs, Johnson & Johnson, Consumer Group of Companies
- Vice President, Chief Medical Officer, Johnson & Johnson, Consumer Group of Companies





Aran Maree, M.B. Ch.B.

Vice President, Chief Medical (Safety) Officer - Janssen Pharmaceutical Companies

Royal College of Surgeons in Ireland – National University of Ireland, MB ChB BAO Hons

Royal College of Physician of Ireland - Member

- Trained in internal medicine and interventional cardiology in Ireland and Australia
- Strategic consultant with Boston Consulting Group  
Medical Affairs & Clinical Research for Merck, Australia
- Market access, Quality, & Professional Affairs (Strategic Medical Affairs)  
Medical Devices, for Johnson and Johnson, New Zealand & Australia
- Vice President, Chief Medical Officer, Johnson & Johnson Medical Devices
- Vice President, Chief Medical Officer, Janssen Pharmaceutical Companies,  
Johnson & Johnson



Question 2: What are the keys to success in Medical Safety?







Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

- Find people that are in a pinnacle role and ask them lots of questions.
- Job descriptions can vary widely between companies, so ask them "What do you do?"
- So that you have alignment between the title or the job that you're seeking and what the job does to ensure that it's, it, it's kind of in line with what you want to do as a career.
- What are the non-negotiables? For example, to be a CMO you likely need to be a physician
- How did they get to their pinnacle role?
- Overlay the paths of how they got to that pinnacle role and what do they have in common?
- What's the next experience(s) that you can identify?
- What do you already have vs. the gaps you need to fill on the road to that pinnacle role?
- I possessed a lot of the skills, but I needed more depth in certain skills.
- So, I anchored myself in one of the key areas along the spectrum to create career depth.
- Ultimately, I leveraged my depth and breadth into Medical Safety as my core competency





Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- You really need is a deep, fundamental commitment to putting the interest of patients and consumers first. Always!
- Here at Johnson & Johnson Medical Safety is an independent function within the company, with a distinct reporting structure free from the influence and interests of Commercial and R&D.
- Consumer products have been on the market for decades. So, you really need to use your best medical judgment and use the data that's available to you to make informed decisions.
- Become very comfortable managing complexity and ambiguity because you don't always have all the information that that you would like, but you still need to make decisions.
- I think people are successful if they really have a deep interest in changing the status quo and really trying to protect patients and consumers.
- In collaborating with multiple internal cross functional partners, you need to be able to break down barriers and work towards a common goal.
- To be able to influence externally requires a high degree of collaboration and trust, whether it's with public health researchers or regulatory agencies.
- In the end, it is about having the courage and integrity to do what is necessary for patient centricity.





Aran Maree, M.B. Ch.B.

Vice President, Chief Medical (Safety) Officer - Janssen Pharmaceutical Companies

- One key learning from my time spent in strategy consulting is the ability to focus in on the details, when necessary, but then when required you then need to then dial back out and see what the larger more global picture is showing you.
- To work effectively and effortlessly across several functions in a highly matrixed environment
- It is expected that you will not only understand every stakeholder's needs but help everyone understand the customer/patient within the larger business context.
- Being able to envision the challenges and what success looks like in terms of health outcomes for all patients is fundamental.
- Learn how to lead in multiple roles, from an individual subject matter expert to a member of a diverse cross functional team or larger business unit.
- Cultivate a genuine willingness to think outside the box of your own comfort zone.
- I think success is about being able to dial up and down your functional verticals but also work across the horizontals. It is something that I have learned by serving in the smaller regional and country roles, that I can bring up to the global organization.
- Your willingness to see the bigger picture and co create a strategy that meets the needs of business is of paramount importance. However, when relevant you always need to be able to get right down to the very pointy end of the patient or customer touch point.





### Question 3: Can you transition between therapeutic areas in Medical Safety?



Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

- Yes, but it requires significant learning agility, you need to be able to pivot.
- At each one of those pivots leverage your strengths and come to rely on them instinctively.
- Where are the fertile areas of opportunities for growth?
- Mindfully recognize what growth opportunities look like and seize them.
- For example, one approach is to examine the total product life cycle for potential career and personal development opportunities across the spectrum.
- Always look at everything in terms of where you're headed and what value you can immediately deliver.





Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- Of course, but you need to be open to learning and developing new skills because eventually someone is going to ask you "Why don't you take on this new area?"
- I think it's about willing to take some personal and professional risks
- Transitioning across therapeutic areas is also for people who are curious
- Whether long or short term have confidence in the strengths that you have and leverage them into a new therapeutic area. Soon enough, you will realize that you can do it.

Personal Example: A few years ago, I was looking for a new career opportunity. One day I was sitting in the office of the boss, and he was struggling in his efforts to recruit a Vice President for regulatory affairs based in Europe. I never worked in regulatory nor had responsibility for the EMEA region, so I thought why not? Soon thereafter I was on a plane with my family flying from Newark to Zurich.

Once there, I developed relationships within the regulatory function by building a new team. Looking back at that transformative experience, it taught me a lot, so much that I could not have developed at the same rate of speed in all of the roles that followed my regulatory VP challenge.







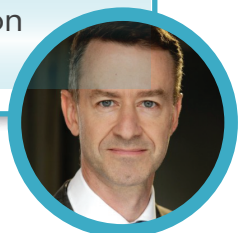
## Question 4: What are the career leadership development opportunities / challenges for Medical Safety?



Aran Maree, M.B. Ch.B.

Vice President, Chief Medical (Safety) Officer - Janssen Pharmaceutical Companies

- Those days are long gone of putting what you know, in the warnings and precautions section of the label and saying that the Medical Safety job is done.
- Being only a vigilant sort of organization or a regulatory focused safety organization is no longer sufficient. So much more is expected.
- For anyone who wants a career in Medical Safety you need to be aware that the real opportunity here is to put the patient at the center of every decision. Namely, optimizing the intended benefits of any medicine or vaccine, while minimizing or eliminating the unintended consequences.
- The Medical Safety strategy across all three sectors of Johnson & Johnson is that we make patient centered decisions.



- We are expected to be medically and scientifically excellent, while bringing ethics and values-based judgment to what we do.
- Fundamentally, from the medical perspective we are the experts in safety, science, and practice of risk management.
- You need to know what the science of safety is and what are the practical implications of implementing risk management, especially risk mitigation and the prevention of adverse events.
- We now must use real world evidence after launch to build on what we understand on the benefits and risks of a medicine or medical device. Namely, how do we use modern techniques of benefit-risk assessment to target and personalize therapies?
- It's not just how we do surveillance, but also the outcomes that we want to try and achieve with our medicines and then, how do we work as a global risk management organization with the medical affairs and the safety officers in our local affiliates around the world to ensure that we optimize health outcomes. We need to optimize health outcomes for the patients who take our medicines in their own country, where different drugs are available, and medicine may be practiced differently.
- A wealth of databases and data sets are available to enable thinking about how we bring risk management to life, beyond the label and try and get this integrated, composite, real time enriched view of benefit-risk and then convert that into practical risk management.
- Technology is allowing access to real-world data sets and how you put disparate parts together along the continuum of drug development and post launch surveillance.
- Be collaborative and work with your Medical Affairs organization, who understands the patients, clinicians, and HCPs in any given environment to best understand how to conduct your surveillance and how best to communicate and optimize benefit-risk. All such collaborations with Medical Affairs should be an ongoing conversation that's data driven, and metrics based.
- In the end, optimizing outcomes for patients is the challenge, the promise, and the beauty of a career in Medical Safety.





## Question 5: How do you evolve from a sole contributor to a people leader?



Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

■ The lesson learned on this journey has been it's never too early to think about your legacy and what you want to be known for

■ Three Leader Questions:

Who do you bring behind you?

What do you leave behind?

What have you learned along the way?





Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- Physicians and pharmacists are deep technical experts.
- As experts we really need to navigate out of that technical mindset and move into more of a leadership mindset.
- Outside of industry in academic medicine or private practice, it's almost like the career progression almost just happens organically by itself. Inside of industry the pace of innovation drives changes much quicker than in clinical practice.
- I think we all need to be thinking a bit more critically and strategically about our leadership careers.
- For example, what are those new leadership skill sets that we want to develop and where do we find those opportunities to acquire those new leader skills?
- It doesn't always mean taking on a new job, but it can be a new special project where there is an opportunity to lead a group of co-workers.
- Look at the senior leaders around us.  
How do they interact with people?  
What are the things that make them successful?
- Finding those people in the company who you really respect and finding ways to emulate them are two great strategies for leadership development.
- There's also learning opportunities for some of those people who may not behave in the way that we want ourselves to behave. Obviously, you can learn from them too.



- There's also learning opportunities for some of those people who may not behave in the way that we want ourselves to behave. Obviously, you can learn from them too.
- So, I believe that every single day is a learning opportunity.
- When I'm trying to build teams, I'm looking for people who have diverse backgrounds that can complement each other to keep the team learning and growing.
- Heterogeneity of thought and experience within a team is crucially important.



## Question 6: Can a career develop across the sectors of Pharma-Consumer-MedTech?



Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- I think it's critically important. If you're going to have a long, successful, and impactful career within industry, you absolutely need to be open to cross sector development opportunities.





At the end of the day, we're all trying to help and do our best for patients and consumers. That is a unifying theme that we all have in common.

Whatever job you have, whatever sector you are in, and whatever function you perform there are learnings that you will take from those experiences and apply them to your next role.



Aran Maree, M.B. Ch.B.

Vice President, Chief Medical (Safety) Officer - Janssen Pharmaceutical Companies

I think we all have a desire to continue to grow and develop.

It's about being clear from a personal perspective on what you enjoy and what your strengths are and those two are not always the same. You need to know the difference!

If you can find where your preferences and strengths overlap that's a good place to begin.

In my opinion that's an important personal exercise, not enough people take the time to accomplish.

You need to think strategically and have a manager that is a very strategic. I've been fortunate to work under a driven leader, with a passion for safety and a passion for developing people.

A leader that knows how to stretch you within your current role and then move you to a different sector to stretch you again is exceptionally rare.



Dr. Joanne Waldstreicher, Chief Medical Officer for the entirety of Johnson & Johnson wants to develop a team of individuals who think strategically around safety.

She built a strong team that focuses on development of individuals and succession planning.

You need to find and work in an organization with managers who take their responsibilities to develop you very personally.

Find yourself a leader that has an enlightened view. One that is keen on taking a risk on people that have the right mindset are they themselves are willing to take a leap of faith with you.

Those kinds of opportunities are appreciated, recognized, and supported. I have been extremely fortunate to be able to have Joanne as my manager over the last nine years.



## Question 7: How do you see Medical Safety ascending into a more strategic leadership role?





Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

- Establishing strategic governance initiatives to pressure test transformative innovation that we are bringing to market from three different perspectives represents such an ascension.

First in Human Committee  
Medical Safety Council  
Development Committee



Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- Consumers are on the forefront of where people as individuals are taking more personal responsibility for their health. They possess critical insights.
- Consumers are using technology to access information to be more engaged in their own healthcare decisions. Therefore, they have higher leadership expectations for us as an industry.
- We need to be at the forefront of bringing better outcomes to patients.



▢ The ability to harness real world evidence and convert it into actionable insights that enhance benefit-risk assessments is the key to strategically leveraging technology for medical safety.

▢ It's allowing us to better connect directly with patients, consumers, and healthcare professionals.

▢ Such connectivity drives a virtuous safety cycle where we're collecting data and we're reciprocally using data to help us better understand how we bring improved outcomes to patients.

▢ Automate the process steps that couldn't be automated in the past.

▢ Take those precious human resources and apply this unbelievable expertise that we have in our people do less processing and more analyzing.

▢ Insights create value. We really earn our seat at the table with regulators, with public health agencies, with health systems, if we can de novo create intrinsic value through interpreting insights that that they do not possess.



## Question 8: How do we prepare our next generation of Chief Medical Safety Officers?





Ed Kuffner, M.D.

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

■ I think you need people who fundamentally understand public health. We need innovative people that are deeply committed to using technology to improve health outcomes for patients and consumers.

■ Expose these committed people to the world's experts both inside and outside of the company.

Personal Example: Exposure to external experts provided me with an understanding of bioethics and being able to apply it in pragmatic ways within the company

■ You will never get away with having people who aren't smart, don't have good medical judgment, and are not confident nor compassionate.

■ In the end, we are all medical professionals and some of us took an oath to "do no harm".



**Question 9: How do you see digital expanding the therapeutic context of the product?**







Jijo James, M.D., M.P.H.

Vice President, Chief Medical Officer, Medical Devices and Global External Innovation at J&J

- Real world evidence is helping us be more proactive rather than reactive.
- New data infrastructure initiatives through the National Evaluation System for Health Technologies (NEST), part of Medical Device Innovation Consortium is leading the way.
- Data solutions can identify unmet needs faster at the outset of product development.
- Proactive post market surveillance will enable us to detect and adjudicate signals much sooner and potentially, proactively prevent issues
- Amplification of the patient's voice and perspective into product development.
- Facilitate faster regulatory new product approvals and label expansions.





**Ed Kuffner, M.D.**

Vice President, Chief Medical Officer, J&J Consumer Group of Companies

- We need people who are digital natives and are deeply committed to using and leveraging such technology to improve health outcomes and stay connected to patients and consumers.
- Again, this is that virtuous cycle I mentioned from patients and consumers to really help them achieve better outcomes.
- It's not just about changing health outcomes; but, especially on the consumer side we are focusing on changing the quality of life.
- Imagining wraparound digital services as an ecosystem for our products can bring us closer to our patients and consumers.
- Digital affords us a way to stay much more connected with healthcare professionals too.
- I think any company that can differentiate themselves through digital technology, where you elevate an average product to another level by demonstrating improved outcomes and quality of life will possess a competitive advantage to drive market share.
- Digital will allow us to influence many people from patients and consumers to public advocacy groups and regulators. It's exciting!

