Wael Adhami and Roy Albiani "on Counterfeit Medical Devices"

Leah Evert-Burks: This is Leah Evert-Burks with the Center for Anti-Counterfeiting and Product Protection @ Michigan State University and *this* is *Brand Protection Stories* - stories about the practice of brand protection by those who live it."

Leah Evert-Burks: In *Brand Protection Stories* we talk to those in the brand protection community about particular cases in their careers. Through some *stranger than fiction* real life scenarios we learn about the practice of brand protection and the challenges faced by brand-owners worldwide."

Wael Adhami: And for us in the healthcare industry, this concern is particularly pressing right because the way health care products are shipped, distributed, stored, handled that has a direct impact on the products efficacy and of course patient safety; and legitimate brand owners in the in the healthcare industry such as Johnson and Johnson abide by strict supply chain measures which at times by the way our government requirements as well, right, to ensure that our patients and consumers receive or administered products that are safe and effective.

Roy Albiani: Well the concerned surgical team notified Ethicon about this suspect product and it was reported to us as a complaint to the quality department for urgent escalation. And we got a sample of this, but suspect, Surgicel, and we got it from the hospital through our quality team, and it was tested by our scientists and when we took a look at it. We found that the product was not only counterfeit, but also nonsterile and bacteria contaminated.

Leah Evert-Burks: Wael Adhami is Johnsons & Johnson's Senior Director for *Global* Brand Protection and is responsible for Medical Devices, Pharmaceutical and Consumer Healthcare in multiple regions of the world including Latin America, Europe, the Middle East, Africa and Asia Pacific regions. In this role, Wael provides strategic direction on brand protection matters for J&J's worldwide regions and works closely with executive leadership teams across the business to protect patients, consumers and their brands from counterfeiting, diversion and parallel import and product tampering. Wael has an

extensive security and international brand protection background and has been heading *related* functions in leading multinational corporations since 2011. Prior to joining Johnson & Johnson in 2016, he spent over a decade in highly volatile environments throughout the Middle East & Africa where he conducted sensitive investigations targeting transnational criminal networks, including in places of detention related to the *Global War on Terror*. As a multi-lingual, published author on international brand protection and security, Wael's international leadership experience is critical in shaping the healthcare environment for J&J, particularly regarding patient safety aspects related to risks from illicit trade. Wael holds a bachelor's degree in International & European Law from Montpellier Law School, in France, and a master's degree in Security & Defense Policies also from the University of Montpellier.

Leah Evert-Burks: Roy Albiani is Director, Global Brand Protection, for Johnson & Johnson Medical Devices, where he leads global strategies to safeguard patients, consumers, health care professionals and brand goodwill against the risks posed by counterfeit, diversion and other illicit trade schemes across J&J's $27B diverse surgery, orthopedic, interventional and vision platforms. Roy has an over 30-year career leading global brand protection, channel compliance, and marketing organizations on behalf of companies with revenues ranging $2M to over $7B. He pioneered Global Brand Protection in 2003 at Johnson & Johnson, which is now recognized as a best-in-class industry leader. Roy has also taught courses at universities, presented at several conferences and authored articles on brand protection. He is a graduate of Western Illinois University with a BA in Marketing and received his M.B.A. from the Cox School of Business at Southern Methodist University.

Leah Evert-Burks: Welcome to you both.

Wael Adhami: Good afternoon Leah Thank you. Pleasure to be here.

Roy Albiani: Hello Leah I'm very happy to be here and excited to share a, what we hope will be an interesting brand protection story.

Leah Evert-Burks: I know it will be. We have talked in a previous episode of brand protection stories about counterfeit therapeutic drugs. No question anything relating to counterfeit pharmaceuticals is always a high priority for regulatory law enforcement authorities, the medical, the medical community, and consumers who are unfortunately the unwitting recipients. Likewise, medical devices, many of which are implantable are also high on the priority list, given the inherent health and safety concerns. Here today, we talked to two leading brand protection professionals from Johnson and

Johnson. Wael Adhami and Roy Albiani, who are dedicated in the fight to protect consumers against counterfeit health care products and found themselves, leading the investigation and enforcement of a case relating to counterfeit medical devices. One, which is surgically implanted to control bleeding in surgical procedures. This case led them around the world and into the operating room. So let's start with a discussion of Johnson and Johnson. Roy, if we can start with you. Can you give us a brief introduction about the company and explain the scope of products of the J&J family of companies.
I know that there's wide categories that carry different risks.

Roy Albiani: Surely Leah I'm happy to. First of all, we're, as you might know, the world's largest and most diverse healthcare company. And as part of that we're committed to use our reach and size for good. And in doing so, we strive to improve access and affordability, create healthier communities and put a healthy mind body and environment within reach of everyone, everywhere. Now one thing that's new news, since we first started preparing for this as you may have heard that recently we announced our intent to separate the company's consumer health business. And so what this results in is creating a new publicly traded company, but historically, our leadership has been in three business segments. So, one that you, most people know as far as consumer health. But we also have a very large pharmaceutical and medical device business. So we kind of break that out just for perspective for 2020. Our sales were about $83 billion. Just a small company. About 50% of that was in the pharmaceutical 30% device, which is what we're going to be talking about today, with the balancing consumer. And just for perspective on medical devices, this segment includes a broad range of patient centric products and solutions used in surgery. We also have in orthopedics division world's largest orthopedics business, vision interventional solutions, which are used primarily by physicians, nurses, hospitals eye-care professionals and clinics. Now, for the purposes of this podcast, we're going to be focused on a counterfeit device connected to Ethicon and Ethicon is our medical devices business. So a little bit of perspective about Ethicon, this is has been in our global franchise, and medical devices for over six decades so been established for some time. And what most people might know us for is that we're focused on a lot of very innovative pressing health care issues. And one of the things that we first introduced to the marketplace that are used every day and ubiquitously around the world are sutures used to. Used to sew one up and you're having a surgical procedure. But we're also revolutionizing surgery, with some very exciting technology for minimally invasive surgery. And if we got a big focus on robotics and digital technology.

Leah Evert-Burks: Very interesting. So Wael I know J&J has a number of credos that you adhere to. Can you tell us a little bit about that?

Wael Adhami: Certainly, so our credo represents the values that are shared among all Johnson and Johnson businesses, functional units and employees. Our credo guides our decision making every day and Johnson and Johnson, and it starts with this sentence and I'm going to read it and quoted directly. "We believe our first responsibility is to the patients, doctors and nurses to mothers and fathers and all others who use our products and services." Our commitment to quality is also the second line of our credo right and state that everything we do must be of high quality. And this of course applies to our medical devices business or from a pharmaceutical and consumer health business, or the products. All the products that we market everywhere at Johnson and Johnson.

Leah Evert-Burks: Great, thank you. So as indicated we are going to be talking specifically about medical devices and Roy I'll start with you again, what risks are there specifically when it comes to counterfeit medical devices?

Roy Albiani: Well, there are many risks, and unfortunately, many medical devices or implantable. And so, let me start first with a general statement, and for listeners if they're interested. We've actually referenced in our counterfeit we've actually referenced counterfeit or 2020 annual report, which is interesting. So we say, you know and I'll read this as well as "counterfeit versions of our product could harm our patients and have a negative impact on our revenues earnings, reputation and business or industry continues to be challenged by the vulnerability of distribution channels to legal counterfeiting and the presence of counterfeit products and a growing number of markets, and over the internet. Third parties may illegally distribute the sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards to distributors and patients counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk patient health and safety, because of the conditions in which they're manufactured often an unregulated, unlicensed, uninspected and unsanitary sites as well as a lack of regulation of their contents. Failure to mitigate the threat of counterfeit could adversely impact our business and reputation by impacting patient competence and our authentic products potentially resulting in lost sales, product recalls and increased threat of litigation." So we take this very seriously, and as a true north of what we do is all about, you know, patient safety. And we're guided by our credo as my friend and colleague, well had mentioned, but if we focus on medical devices specifically, and the consequences that we have with a particular product

called Surgicel it can cause serious injury or even death. So as an example, what we're going to be talking about for the balance of this discussion is counterfeit Surgicel. And this could result in very serious harm to patients because what we found is that these products have been contaminated with bacteria. They're nonsterile. And in addition to counterfeit is unlikely to effectively control bleeding during a surgical procedure so you can imagine. This is by the way a staple that's used in virtually every operating room in the world. That's use got oftentimes a suture and so forth. But during surgical procedures, if this product isn't absorbed properly could remain in the body as a foreign object leading a serious complications or even death. And this is what we're talking about with the counterfeit Surgicel.

Leah Evert-Burks: Right, right. So thinking about devices making their way to the operating room as you just indicated. Roy can you explain the supply chain for medical devices to healthcare facilities?

Roy Albiani: Sure is, speaking for the U.S. Johnson and Johnson medical devices they're typically distributed through what we call authorized wholesalers, these are wholesalers that have been vetted you know by Johnson and Johnson, they have to sign agreements, which would indicate that they would only source the product from us, and therefore they become, they become authorized sources because we're very worried about the introduction of product into the supply chain is not legitimate. So we either distribute through these authorized sources, or directly to hospitals and other health care facilities to be used in surgical procedures by healthcare professionals. So to avoid risk to patient safety, we recommend that health care facilities, only buy directly from J&J, medical device companies for their authorized distributors.

Leah Evert-Burks: Okay, so we've talked in brand protection stories before about this term, but Wael can you explain what the gray market is and how unauthorized or counterfeit devices can enter the supply chain?

Wael Adhami: Sure. So gray market is also referred to as, the depending on you know companies and sometimes geographies right, as parallel trade, secondary market, diversion right so it really depends, but ultimately what that refers to is the trade where goods are redirected from the manufacturers intended area of sale or destination to a different geography or distribution channel without the authorization of the legal brand owner. Right? Now that being said, in certain jurisdictions, such as the European Union, for example, parallel trade is legal. However, there are clear regulations and requirements in place to ensure that this is done in compliance with European laws, but also in a way that preserves patient and consumer safety, right. Where a gray market or parallel trade or diversion is not

legal and not regulated, the risks that we often see are in relation to how these products are being handled outside of the authorized supply chain of the brand owner or manufacturer. And for us in the healthcare industry, this concern is particularly pressing, right, because the way health care products are shipped, distributed, stored, handled that has a direct impact on the products efficacy and of course patient safety; and legitimate brand owners in the in the healthcare industry such as Johnson and Johnson abide by strict supply chain measures which at times by the way our government requirements as well, right, to ensure that our patients and consumers receive or administered products that are safe and effective. Now unfortunately, illegal parallel importers and the voters do not always follow the safety standards and thinking of where these illicit parallel importers of way marketers are sourcing their products from. I mean, this is usually done you know through entities that are not authorized by the brand owner, and among other things that can result in counterfeit tampered expired short- dated products stolen goods products without instructions for use required by local regulatory agencies, being introduced into the supply chain. And all of these factors, and many more. By the way, can present serious risks to patient safety. We should also speak of course on how these illegal parallel importers evade taxes duties that cause substantial income loss for many governments around the world

Leah Evert-Burks: Right.

Wael Adhami: Now, unfortunately, what happens is, in an effort to save money versus sources that are authorized by the legal brand owner, some health care facilities around the world may sometimes choose to procure products from the gray market, which presents risks, not only to the patients, but to the reputation and integrity of the healthcare facility and national health care systems, really. In all cases where we've identified counterfeit, including the brand protection story that we're about to reveal it has been introduced through the gray market.

Leah Evert-Burks: Okay, thank you for taking us through that because it really does lay a foundation for as you said the case that we're about to talk about it. Roy as you indicated, We're going to be talking about an implantable medical device called Surgicel. Can you kind of take us through that case and the discovery.

Roy Albiani: Sure I'd be happy to and, you know, first, I think it's probably helpful for our listeners to provide a little bit of background about what Surgicel is, so surgery cell is a topical absorb human stat, so it's a fancy way, we've got a device that's used to control bleeding during surgical procedures, and these products have been sold by Ethicon for more than 60 years and used in more than 150 million

surgical procedures worldwide. So it's, it's very well known by surgeons and as I mentioned, it's a staple, but you know it's used in in surgery, so it's got tremendous brand equity and associated with goodwill. Unfortunately these positive attributes also make it a primary target for counterfeiters.

Leah Evert-Burks: The discipline of brand protection is derived out of trademark law since counterfeiting is a violation of trademark rights – its important to remember that these are laws set up regionally throughout the world to protect the consumer. Yes, trademarks are assets of companies, but they tell the consumer the source of the goods and provide the assurance of origin. But, brand protection isn't only the responsibility of the legal profession, it's a multi-disciplinary by nature, *and* necessity. People find themselves in this field from such diverse career paths as security, supply chain, law enforcement, marketing, IT, finance and yes legal, as well as many more.

Roy Albiani: Now, I'd like to share that this counterfeit issue was discovered when a neurosurgeon was conducting a craniotomy. A very serious surgical procedure. He noticed a problem with what he thought was Surgicel as he was about to introduce it into a patient's brain. Specifically the product was not folded up properly in the packaging so he noticed this and and made us aware of what was happening and the device kept rolling up after being cut into shape so something unusual is going on.

Leah Evert-Burks: Wow, so once discovered, how was the issue escalated?

Roy Albiani: Well the concerned surgical team notified Ethicon about this suspect product and it was reported to us as a complaint to the quality department for urgent escalation. And we got a sample of this, but suspect, Surgicel and we got it from the hospital through our quality team, and it was tested by our scientists and when we took a look at it. We found that the product was not only counterfeit, but also nonsterile and bacterially contaminated. So the thing that we're very concerned about here is, you know, both the product packaging and the device are counterfeited and given the facts that we've identified we were very concerned about the threat to patient safety. And so we immediately formed a broad global brand protection security investigation, in partnership with our global security team, and a number of other business partners and advisors to help us get after this.

Leah Evert-Burks: Can you walk us through how you approached that global investigation and those enforcement actions?

Roy Albiani: Sure, be happy to. So, in this case, or counterfeit mitigation strategy had two goals. So the first piece is we've got to do everything we can to quickly safeguard patients. And then secondly, we

want to dismantle, what we call the global illicit supply chain. And so what we're talking about is, you know, not just one hospital where this occurred, but we've got to go across regions and geographies to really figure out where this is coming from, who's manufacturing this, you know where's the packaging being produced and all the raw materials and components. So this is you know this is where Wael and his team have come in and have been so helpful in this, this whole matter. But the source of the counterfeit received by the hospital was identified to be a gray market wholesaler based in Florida, and as Wael had mentioned, this is the source of all the counterfeits that we've identified are typically through gray market wholesalers, so creatively this this company is called XS Supply. We learned that the entity was found to have sold hundreds of counterfeit Surgicel devices which was was very concerning and quite disappointing. So in parallel with the investigation, our team executed a, what I would consider to be a robust market intelligence campaign. And this allowed us to acquire hundreds of counterfeits and identified additional counterfeits suppliers. So to mitigate the imminent danger to patients, we pursued a civil enforcement remedy which we have used a number of times in the past, at least here in the U.S. And this allowed us to obtain a court order that immediately stopped the distribution and sale of the counterfeit from XS Supply and the other benefit we got was a court order that provided us with what we call expedited discovery meaning that we're able to go into the premises of XS Supply, another gray market wholesalers, seize documents and records and image cell phones, hard drives and so forth. So this action you'll get some tremendous insight regarding the illicit supply chain to include, where was this product coming were coming from, and where it was, where was it going and so forth and so based on that we started to work our way up the food chain. And what we understood and what was revealed, was that the, this gray market wholesaler XS Supply was supplied by yet another Florida- based gray market source called Lionheart. And this entity, was named as a codefendant in the case. And when we did the discovery at Lionheart, we learned that the proprietor, and her partner got the product from an illicit trader in Dubai so the plot continued, and it now reveal that we had a problem, you know outside the US.

Leah Evert-Burks: Counterfeiting can be lucrative but in many jurisdictions prosecution results only in low penalties, therefore it attracts a wide spectrum of criminals from out-of-garage sellers to sophisticated networks funding terrorism. And what is counterfeited? Just about everything.

Leah Evert-Burks: And in so many cases there are so many layers that you peel back. So, so you discovered that there was an illicit trader in the United Arab Emirates. What were your next steps following that discovery?

Roy Albiani: Well, yes, interesting, working across the regions with Wael's team. We, and also outside counsel on a number of other external partners. We were led to from Dubai to an individual, Pritamdas Arora who was counterfeiting Surgicel, and he was what we would call a kingpin, proprietor of illicit devices supplier called Medserve in Delhi, India. Unfortunately, this this person, and his company had also been implicated in selling counterfeit contaminated mesh in the US, before for another company, not Johnson and Johnson, but in that particular matter, a law enforcement stopped at our borders and didn't go beyond into other countries and this individual continued to engage in illicit trade. So we were hoping from the actions that we've been taking here that we could stop him, you know permanently. So, what we learned was that from the discovery in India, it was revealed that Medserve sold thousands of counterfeit devices to at least nine countries that we know of, across all regions of the world, so this this one individual area that was revealed that a hospital in Kentucky. Now, was at least nine countries and it became more and more concerning based on the discovery that we had so having this revealed we engage with outside counsel in India to proceed with civil enforcement, where our objectives are essentially the same as in the U.S. So we wanted to stop the distribution and get injunctive relief to do that. And we did a product seizure, and it was at the target's Delhi apartment floor where it was revealed there were thousands of these counterfeit Surgicel packages. And it was very egregious and concerning because what we found from our discovery is that he was taking these contaminated packages that some place was producing likely in India, and they're being filled on a floor with non-sterile gauze-like material he had sourced from Turkey, of all places. And so, ironically, during the seizure, another counterfeit product was delivered by were there and it was coming from China, so it's just amazing what we're able to reveal, you know, during this effort. And so, with the civil enforcement were able to achieve injunctive relief prohibits Arora from the continued sale of counterfeit or be faced with substantial penalties, including prison.

Leah Evert-Burks: And just to remind the listeners, again you're talking about the condition and the non-sterile nature of these products, these are implantable medical devices and as you indicated first discovered by our neuro neurosurgeon for brain surgery so just to emphasize that point. So, this became a global investigation. I'd like to turn to Wael and if you could tell us what happened next.

Wael Adhami: Absolutely. And it's, it's actually one of my, you know, my favorite pieces of the puzzle because it's gives me the opportunity to also, you know, really thank the the law enforcement agencies around the world. The incredible professionals that we partnered with in countries such as India

and China and Pakistan in the U.S., right, and thanks to them, you know, we were able to to disrupt this dangerous and you know transnational counterfeit network sending these highly sensitive medical devices. So as I was mentioning right we had the civil enforcement activities in the U.S. and in concert with these, we collaborated with law enforcement agencies in various jurisdictions around the world. So think of the U.S., India, China but also Pakistan. Right then, the goal in each of these investigations was criminal prosecution in order to make sure that the counterfeiting would just stop, right, that was the number one objective. And these activities have been a very important and critical part of our collaboration with law enforcement agencies around the world, and the discovery process helped to produce a persuasive case for further prosecution. Right, now the initial investigation the U.S. that Roy, you know, provided some details on revealed multiple suspect transnational links with major players, and this counterfeit operation, based in India and Pakistan and in China. Now again we alluded to this before but we're privileged to have and lead a global brand protection team where our footprint in these countries is very well-established, right, and our team quickly sprang into action and kicked off simultaneous investigations across these countries. Now in India, and Roy you mentioned this before, right, our investigation reached the major source of counterfeit exports for surgery so. And that was a that was a massive win, obviously for patient safety. In China, we managed to also identify the main source of these counterfeit Surgicel products, leveraging the intelligence collected during our India investigation. And recently, actually the law enforcement authorities in China, successful enforcement actions against these illicit traders and now we are in the process of evaluating further actions on the ground. Now Pakistan was also another key point of focus in our global investigative efforts so intelligence from our investigation in the US and India, show the strong connection point with specific traders in Pakistan. And our team conducted thorough investigations on the ground spanning across multiple cities, and several months. Ultimately, culminating in the seizure of over 70,000 individual Surgicel products, and the rest of the individuals involved - now again over 70,000 individual kind of facilities sell products, it's it's absolutely staggering. Right? This is thousands of operations and thousands of patients that are now rest assured that they will never have to see these products, administered to them.

Leah Evert-Burks: Right, it is staggering. So thinking about the timeline of this case. Roy, how quickly did you, did you move from discovery to investigation and then shutting down the operations?

Roy Albiani: Yeah, I'm happy to speak with that Leah so those began in an operating room in one hospital United States, and it started with one actual actually one complaint, as well, and who knew that this would just be the tip of the iceberg, but you know what was discovered in an operating room in one hospital in the US was revealed to be a global issue. And as I mentioned earlier, we knew that it appeared in at least nine countries that we know of, and we know that because of the wonderful discovery that we got from the civil enforcement actions that we took. But during our discovery, we learned that more than 250,000 units of contaminated can counterfeit surgery cell, and other medical devices that were counterfeit originated from and were sold by Arora, the India source, and in our collaborative global security investigation and civil enforcement actions resulted in the identification and dismantling of a very dangerous international counterfeiting scheme, and I'm proud to say we did it in less than six months, and you know the civil actions that we took the investigations, the collaboration across regions beyond our borders in the U.S. and around the world, resulted in this - this execution and less than six months which was really unheard of, you know, in the past, given the scale of what we were seeing here. And now the, the investigation also prevented the continuation of the sale and distribution of hundreds and thousands of units of contaminated counterfeit Surgicel into healthcare facilities, and that was really the most important thing, because it's all about patient safety and we believe that we may have saved many patients from great harm by or activities, or even death.

Leah Evert-Burks: Right, and and quick response as you said, less than six months.

Leah Evert-Burks: Roy Albiani was the 2020 A-CAPP Brand Protection Hero. The Brand Protection Hero Award recognizes significant contribution to the field of brand protection and to combating product counterfeiting. It honors an individual who has demonstrated commitment and added value to brand protection, either by a single act or over time, in a way that exemplifies the highest standards of performance and integrity and advances the field. Nominees may be from industry, government, academia, or other sectors of the field. See the December 2021 edition of *The Brand Protection Professional* and be introduced to the five 2021 A-CAPP Brand Protection Heroes of Latin America.

Leah Evert-Burks: So, Roy, thinking about the courses of action that you took what U.S. actions spun off of these investigations?

Roy Albiani: Well you know it's funny because when you go into these things, you know what you know and then as you get more discovery you learn more and more. And we got an incredible intelligence from these civil actions both in the U.S. and India. And what we learned was that one of the largest gray market wholesalers and medical devices in the world, based in Illinois a company called eSutures was trading with Arora, and other parties. And sadly, this company was also distributing counterfeit. In the U.S., and other other places. And that's a separate story into itself that perhaps we might record in the future. But in the case of the eSutures, what happened is we did a enforcement seizure, again this was another civil matter. And it was a $25 million seizure which is the largest that we know of in the world of healthcare medical devices.

And as we speak we just finished destroying this massive quantity of illicit devices. It was a tremendous undertaking millions of devices that were destroyed and, and taken off the market and potentially causing patient harm. In addition, as part of the terms of our settlement, eSutures and his proprietors are permanently prohibited from selling any products within the Johnson and Johnson family of companies. So that was another nice win. Now, we also continue to partner closely with law enforcement to pursue criminal charges in various parts the countries in the world, including partnership with Wael's team, and law enforcement and as a recent example Janaina Nascimento who is the proprietor of Lionheart the Florida based gray market wholesaler who imported the counterfeit Surgicel into the U.S., she was sentenced, and she is currently serving her time.

Leah Evert-Burks: Hmm. So reflecting on this case, I'd like to hear from both of you as to what this experience changed in your practice for Johnson and Johnson and we'll, we'll start with Roy.

Roy Albiani: Okay, so, you know, in addition to our enforcement actions you know we talked about the strong defense, because I'm a Chicago Bears fan and so is my friend Wael, so it's all about strong defense to keep our patients safe but we also look at doing things that are proactive. And so one of the things that we're really focused on is the deployment of what we call proactive end-to-end anti-counterfeiting programs. So what can we do to proactively prevent or minimize future impact to patients. And at the same time protect the goodwill of our brands. So you know, these, these programs are becoming a standard approach for how we address products at high risk for counterfeit, which could result in in harm for patients and consumers so you know typical elements of these programs include you know the introduction of product security features that allow us to quickly identify counterfeits in the field. And also proactive market monitoring, so as many different tactics that we use, and antennas that

are out there to help us identify these concerns. And then, when we identify these risks across the globe, we take action, and we also have an area, a robust focus on what we call illicit trade analytics. And this helps us to measure risk in business impact as you can imagine we have 10s of thousands of brands and products around the world, but they don't all warrant the same level of priority and this helps us to really help us understand our risks which my friend Wael is going to speak about that a bit more.

Leah Evert-Burks: Yes, if you could Wael.

Wael Adhami: Yeah absolutely and and Roy really you know you're, you're spot on when you mentioned the illicit trade analytics right because that's also one of the big you know projects that we've been running in an effort to become somewhat more preventive as well it as it relates to these risks and we've introduced analytical tools to assess counterfeit twist. So for example, we deployed a new prioritization tool that analyzes data from various sources to determine the brands at greatest risk for illicit trade. We call that our Segmentation Tool right and we use market and business intelligence and multi-year internal data to improve our decision making in the best interest of patient protection.

Leah Evert-Burks: It's a good way to to take the data and the information that you've obtained and be able to use it moving forward. So that's, that's interesting to hear about the Segmentation Tool, and also deciding on resources. But thinking about the gravity of this discovery and the information that was gathered. How did J&J communicate with the healthcare population on the discovery of the counterfeits, and I think Roy I'll turn to you on this, this one as well.

Roy Albiani: I'm sure happy to take that Leah and, you know, given the concern, you know felt like we had a credo obligation for us to, even though it was not our product. We knew that it was dangerous and it looks an awful lot like our product and patients, or I should say health care professionals could be very confused by what they see. And so we felt like we needed to communicate about this and we did. So we talked to our healthcare customers and regulators to make sure that they are aware of the counterfeits, and we shared with them reminders about how to safeguard their supply chain, and you know again foundationally the way to do that is to purchase medical devices from sources authorized by Ethicon in that gray market sources.

Leah Evert-Burks: Mm hmm. Absolutely. So, I want to thank you both for walking us through this important case and in such detail from the discovery of the counterfeits in the operating room to peeling

away for us how this happened, and the lessons learned. And one final question for both of you. If you could choose one word to describe this case, what would it be? Roy?

Roy Albiani: I would use is purposeful and, you know, just the work that we do each day, and global brand protection, truly has purpose and meaning we're making a different difference in. We're making a difference for Johnson and Johnson, and the equity of our good name that, you know, millions of people around the world. Recognize Johnson and Johnson for, and the work that we do at Johnson and Johnson, really directly ties to our credo which guides our actions and our responsibility. The first of which is to patients, doctors and nurses and I have to believe that each day we make a significant impact around the world to safeguard patients, and the integrity of the supply chain from counterfeit.

Leah Evert-Burks: I would agree. And Wael what word would you select?

Wael Adhami: I would use impactful. Right. And the reason why I say this is because I believe this specific case has had a significant impact on on many levels right so first of all, think about the substantial volume of counterfeit medical devices that this investigation, you know, in collaboration with our global security partners in collaboration with a law enforcement professionals around the world, right, has managed to take out of the market and what that means in terms of patient safety thousands of patients around the world that don't have to, you know, ever see these products be being administered to them. Right? And impactful because it went beyond the geographical scope of one specific country. Right? I mean you know these are investigations that were conducted in several countries and, and from each of these countries we identify that there were networks involving other geographies as well. So by taking down this transnational network, it really had a global impact on patient safety and therefore, I believe impactful is, is the word I would use for this specific investigation and case.

Leah Evert-Burks: Absolutely. So I want to thank both of you for doing the hard work and protecting the world's consumers.

Wael Adhami: Thank you Leah

Roy Albiani: Thank You Leah, it's been a pleasure.

Leah Evert-Burks: Many companies and brands are unwilling to talk about counterfeiting, many, for fear that the mention of the existence of counterfeits of their products will damage their reputations, and possibly move consumers and customers to competitors. I commend Johnson & Johnson for their willingness to talk about this important case, in such detail, and their willing to disclose information on

the threat and risks of counterfeiting in their 2020 Annual Report. Living up to their credo of "We believe our first responsibility is to patients, doctors, nurses, to mothers and fathers and all others who use our products and services.

Leah Evert-Burks: If you're interested in sponsoring episodes of Brand Protection Stories, please contact A-CAPP Assistant Director Kari Kammel at kkammel@msu.edu.

Leah Evert-Burks: In the next episode, former Department of Justice prosecutor John Zacharia discusses counterfeit pet medication. Medications that reached the shelves of a major U.S. retailer. Find out how this criminal ring operated and as the allegations state, even used sympathies for hurricane relief to get their product into the U.S. We love our pets like family and this story hits home.

Leah Evert-Burks: Thanks for joining us today for this edition of *Brand Protection Stories*, produced by the Center for Anti-Counterfeiting and Product Protection (or A-CAPP) @ Michigan State University in East Lansing, MI. Please visit us @ a-capp.msu.edu. A-CAPP is a non-profit organization founded in 2009. It is the first and only academic body focusing upon the complex global issues of anti-counterfeiting and product protection of all products, across all industries, in all markets. In addition to this series, we offer certificate courses in brand protection, applied education and academic courses, executive education, student internships, live summits and virtual events, ground-breaking research, and publish the quarterly digital industry journal, *The Brand Protection Professional*.

Leah Evert-Burks: This is Leah Evert-Burks with A-CAPP. Until our next session, keep protecting your brands, and the world's consumers. Keep it real.