Across the Wavelengths

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I am an inventor by nature. I love creating and telling fantastical stories. I am mesmerized by advances in science, and I have always been intrigued by the great creations of our ancestors and coming up with my own ideas.

So many great innovations today can be classified as modifications of some form or another of previous inventions. If it wasn't for the long list of great scientists and philosophers of years past, I would not be able to stand here today and talk about how sunlight has a multicolor composition. We call these wavelengths colors, at least all those in the visible range. These visible colors are made of Red, Orange, Yellow, Green, Blue, Indigo, and Violet, the colors of a rainbow. You might remember the acronym ROY G BIV from school.

Most of us, at one time or another, have seen a rainbow, and perhaps you may have a specific memory of seeing one for the first time. Reflecting on my past, I recall the very first time I saw a rainbow growing up in Italy. In Italian we call it arcobaleno. It was on a very hot summer evening in a little town called Valenzano, just a few kilometers on the outskirts of Bari, Puglia a very far south city in Italy. You see, I was a rather gangly, energetic little boy who enjoyed playing street soccer (futbol) with my best friend, who also happened to be my brother, Giovanni. I was also a very curious little boy who loved to invent fables. I was a visionary storyteller. On this dark cloudy day while playing futbol a down pour "kicked us" off of the streets. We ran for cover under a balcony because we were forbidden to get wet in the rain. As a husband with three kids and practically half a century on my shoulders I now know that Italians are recognized for a lot of great things, but I also have come to know that we have many unsubstantiated beliefs. One of these beliefs is that you will catch a cold if you get wet from the rain water, as if the water itself is carrying the cold bug. Another unsubstantiated belief is that if you see an arcobaleno, do not dare point to it with your finger. If you do, something bad will happen. So there I was under the balcony with my little futbol group and I was telling them their favorite fable of a flying white horse while waiting for the rain to stop.

Just then I saw a very beautiful site, my very first site of the arcobaleno. It was up high in the sky reaching from one end of the small town, stretching over the tree tops, clear to the other side of the town. I was in awe! I remember that moment being magical. I was in a trance, almost mesmerized by its beauty. Immediately, the sound of the rain and lingering thunder and all of my friends' voices faded around me and I was locked in a moment of serenity where nothing else mattered. Slowly, I began to think about doing the unthinkable, point to it. Suddenly, I *had* to point to it. A force from above was attracting me to point to it. So I did! Slowly and timidly I raised my arm and pointed to the arcobaleno. Then I closed my eyes out of fear and in my mind I thought I was going to die or disintegrate, but neither happened. Obviously outside the wonderful and magical site of an arcobaleno, technically speaking, it is a reflection of the sunlight travelling through water droplets in the sky acting like prisms. It is an example of spectroscopy.

This marriage of magic and knowledge is what drew me to becoming a scientist and led me to working in the laboratory for The Food and Drug Administration's Forensic Chemistry Center (FCC) here in Cincinnati for the last 20 plus years. The FCC was formed in 1990 from a research group led by my dear friend and father figure Frederick Fricke. It was actually founded on spectroscopy techniques and today the laboratory houses a lengthy list of state-of-the art analytical abilities. In over two decades that I have spent at the FCC, I have had the great privilege of working on a wide array of projects and cases.

I remember when I first started working in the laboratory being tasked with injecting potent poisons into foods and beverages and performing time studies to give us information in preparation for any potential terrorist attacks on the food and beverage supply chain. One time my friend and colleague, Marty Votel, and I were working and we became quite literally overwhelmed by the stench of rotten eggs. The smell was coming from a colorless and potentially deadly gas, hydrogen sulfide. No matter how much I tried to calm myself down, I ran outside of the building hoping to make it out in time to catch breaths of fresh air. Although, for a moment I believed that I was going to die, Marty and I were soon filled with laughter at our shared stupidity.

A couple of years later I moved on from injecting fruits with poisons to working on tampering cases. In order to be skilled at tampering analysis, you need to be able to put yourself in the mind of the criminal. It may sound alarming to you, but I actually excel at this. I think all of the

stories that I invented as a kid have actually found a useful purpose. But in all seriousness, product tampering can have a devastating impact on consumers and businesses in the US. One big reason is that once the news of tampering is reported and publicized in the media it usually triggers “copycat” offenders. A very good example of this was in the 1993 Pepsi syringe scare. FDA offices around the country as well as state and city police were inundated with cases related to reports of Pepsi tampering as a result of nationwide news media coverage. A couple of hundred of cases, each reporting to contain foreign object(s) in soft drink cans, came flooding into our laboratory in a very short time. All of that work resulted in multiple arrests and convictions.

Another case that stands out in my memory involved working with the Indiana State Police (ISP) Crime Laboratory and assisting them in an investigation of rubber pharmaceutical vial stoppers. After years of working on tampering cases, I had developed an expertise in image analysis and needle punctures. This investigation revealed one of the largest mass murders in Indiana’s history involving the serial killer Orville Lynn Majors, who was given the name “Angel of Death”. It was reported that he injected potassium chloride in the IV lines of his patients, and most of his killing were believed to be “mercy killings”. Through successful analyses and investigation, Majors was convicted of six murders. However, it is suspected that he is responsible for more than 145 murders. He received a sentence of life imprisonment.

Another case that unfortunately stands out in my memory involved a woman with a drug addiction problem. All too often our laboratory receives vials which are supposed to contain controlled substances, but the vials have been tampered with and the drug is removed and is replaced with saline, or worse tap water. The Lynn Ellen Schneider case involved a nurse in a Washington state hospital who had tampered with 100+ glass vials. This case troubled me more than other glass vial tampering cases because during the trial in the courtroom, as I was testifying as an expert witness, there were several instances when my eyes would lock with the defendant, Ellen Schneider for brief periods of time as she sat a mere 15 feet away from me. A jury decided that Ellen would face a maximum penalty of 10 years in prison and a $250,000 fine. However, after the jury made that announcement, we were told that a day later Ellen committed suicide. I was deeply saddened by that news.

Not all of the work that I have done at the FCC has involved product tampering. An emerging and prolific problem in the pharmaceutical world is counterfeit drugs. Counterfeiting is a twist on tampering because rather than taking an existing product and altering it, people are creating new products to *look* like existing products. Over the last 15+ years, there have been growing concerns of criminals viewing drug counterfeiting as a lucrative business with little jail time. Pharmaceuticals used for the treatment of cancer and AIDS and immune boosting for weakened systems are often counterfeited because these drugs are very expensive to buy. Just as recent as last year the FDA reported that the drug Avastin, used for colon cancer, was found to have been counterfeited; one simple reason, a staggering $50,000+ for a one year treatment.

In 2003, a Lipitor case arrived in our laboratory which showed us with staggering clarity how sophisticated counterfeiters had become. After analyzing a large number of tablets and comparing the results of the physical analysis with the results of the infrared spectroscopy analysis, it was discovered that something was not right. The results were found to be conflicting. How is that possible? The physical examinations of the tablets were found to be consistent with the genuine products, while the infrared spectroscopy was not seeing the active ingredient, atorvastatin. So what was it? The tablets physically looked identical to the genuine tablets, but no active? As troubling as it was having conflicting results it was later determined that both techniques were correct. Again, how is that possible? Tablet making requires stainless steel tablet punches, to punch out tablets with debossing characters on each tablet. However, fake tablet punches would have easily been caught by our trace section, using 2D and 3D image analyses techniques. What further investigations revealed was that the criminals were able to get their hands on actual Pfizer punches. They had drafted up a genuine looking order letter, with Pfizer logo, letterhead, and signatures. The genuine tablet punch manufacturer, after receiving the letter, then filled the order with brand new punches and shipped them to the pseudo extended Pfizer site.

This was just one example of counterfeiting. This problem was becoming huge and analyzing all these tablets was taking way too long. I had to find something that would shorten the analysis time. I also needed something to help the investigators find these counterfeit tablets and be more selective in the number of samples sent to our laboratory because they were just sending everything and bogging us down. In 2005, I essentially hit my lucky day. I thought of

examining some of these fake Lipitor tablets under a black light, an ultraviolet light. Unfortunately, that did not work, but in that moment the magic of my old friend arcobaleno hit me and I thought, “what about ROYGBIV?” In the laboratory we have a bench size crime scene light source, which is an instrument that only has some wavelengths (colors) that make up part of ROYGBIV. I decided to try it and by golly it worked! In that moment I couldn’t contain my excitement. I yelled out “Mamma mia che bestiale!” Two colleagues of mine, Frank Platek and Mark Witkowski, came over and asked me what was so exciting about Lipitor tablets. I showed them the exciting and promising find. The suspect Lipitor tablets looked different under the light compared to authentic tablets. This could be a huge help. Microscopically analyzing just one bottle containing 250 white tablets would take me one to two days. Now with this promising method I could scan through an entire bottle of tablets almost instantly. I was able to pour out an entire bottle of suspect fake Lipitor tablets and within a minute I could mark that bottle as done.

That evening as soon as I got home I immediately pulled out my Cambridge notebook and my Staedtler Mars Lumograph HB drafting pencil and started sketching out a miniature hand held alternate light source. The very next day I placed an order online with Mouser Electronics for all my needed electronic components. I purchased all the parts out of my own pocket. I didn’t want to wait a single day, and it would have taken too long to purchase them through our purchasing agent. However, in my excitement, I didn’t stop long enough to think about how I was going to miniaturize the high power 300W Xenon bulb and the rather large color filter wheel I would need for this device. Two days later, all my electronic components arrived at my house, but I was still trying to figure out how I could miniaturize a 1 inch diameter by 3 inch tall Xenon bulb into a size that would fit into a plastic enclosure basically the size of a TV remote. Any small bulb, even a tungsten bulb, would be too big and would get too hot for a plastic container. A month later, in January 2006, I still had not figured out what light source to use and all my plans were still on hold. On one snowy day, my colleague Frank and I ate our lunches in our offices. Frank wanted to show off his new Christmas toy. He walked up to me and within two feet from me he flashed his key chain light in my eyes. It was an extremely bright light that hurt my eyes. Even in 2006 light emitting diodes (LEDs) were just beginning to show up in consumer markets. LED technology was new to Frank and to me so he couldn’t have realized the intensity of his new toy. But instantly I literally and figuratively saw the light.

“That’s it!” I thought. I asked Frank what was that light. He said “LED?”, in a question. I asked to see it and that’s when I realized that was the light source I was going to use. It was incredibly bright and it remained cool to the touch. Right away, I began reading about LEDs to understand how they were made in order to understand how they worked and I discovered that they come in the full ROYGBIV range. I was euphoric! I had found a light source available in all colors, and beyond. I had found a light source that could enable the creation of my own arcobaleno. I felt like a poet and the words just spilled into my mind “I visualized a curving path of coloured lights, flourishing from sun light that peek through fissures of dark clouds forecasting a daunting storm”.

From the beginning I envisioned a small hand-held device that was low cost, easy to use, and provided the ability to scan lots of products very fast. I also wanted to develop a device that would allow seeing counterfeit drugs and their packaging noticeably different from the real thing even to the untrained eye. The initial work was all done on my kitchen table. After endless hours of testing various types of LEDs and electronic components and configurations I finalized the prototype. After, testing numerous finished dosage pharmaceutical products and confirming the findings with other laboratory techniques the device was given the name Counterfeit Detection device version 1, CD-1. Over the last seven years modifications gave birth to the CD-2. In 2010 the latest version was born, the CD-3, which included an internal library of information about authentic products so that the originals do not have to be on hand to compare with drugs being tested. With the addition of the libraries, the device could even be used at remote locations and its cost was still a fraction of the price of existing hand held or mobile technologies. Until 2012 the device was kept within the folds of the FDA and a few other federal agencies. However, in June of last year, The Center for Disease Control (CDC), Division of Parasitic Diseases and Malaria and FDA headquarters envisioned the CD-3 as a global support tool. In July 2012, I was asked to pilot the CD-3 outside of the United States. We had reports from the CDC that a young child in Africa dies of malaria every minute. We also had reports that as high as two-thirds of anti-malaria drugs available in Sub-Saharan Africa and Southeast Asia were counterfeit or substandard. Since malaria is a global concern, the first selected testing site was in Laos in South East Asia. So, I was immunized and shipped off to Laos. I was there to evaluate the CD-3 for the detection of counterfeit anti-malarial products. The CD-3 was evaluated using 232 samples of multiple brands of anti-

malarials compared to authentic products. The results were compiled and the specificity and sensitivity of the CD3 for detecting counterfeit anti-malarial drugs was calculated to be 97.4%. Only two authentics were misclassified as counterfeit based on available comparison. The remarkable South East Asia pilot results initiated a cascade of interest. The excitement sparked the FDA commissioner, Dr. Margaret Hamburg, to call for a press release at the 2012 "Science Writers" symposium to announce the FDA's commitment to protecting the American people by announcing FDA's very own created device, the CD-3. Dr. Hamburg revealed that the FDA was using this new innovative technology to improve its inspection capabilities. Once again as many years ago, I slowly fell into a trance just as when I first saw the arcobaleno. As questions from the press were shouted I sat there next to my laboratory director and the FDA commissioner and all I could feel was a sense of pride and magic. I couldn't believe it. Margaret was announcing my dream, my arcobaleno to the world.

Following the FDA's commissioner's announcement, the device was submitted as an innovation to the 2013 HHSinnovates Program. The program recognizes inventive and original projects led by HHS employees designed to help solve some of the nation's most challenging health care problems. On March 19, 2013, out of 45 submitted innovations, the CD-3 team was selected by HHS Secretary Kathleen Sebelius as the 1st Place Winner. The momentum of the CD3 continues to grow, and on April 25th, 2013, the FDA Commissioner will announce a public-private partnership to commercially produce devices for use at home and abroad. In the very near future the CD-3 will piggyback on existing organizations engaging with the U.S. Agency for International Development (USAID) in a deployment to Ghana, Africa, then the Mekong Delta, where extremely sophisticated anti-malaria counterfeits have been detected.

Who would have ever thought that this little boy's dream of rainbows would be used someday to help so many and go global. This invention has been the perfect fusion of the magic of the arcobaleno, my passion for good stories and adventure, and my love for the genius of science. Currently, I am working on finalizing a new device. This device incorporates all the features of the CD-3 with added wavelengths, ranging from deeper infrared, across the ROYGBIV, and into deep ultraviolet wavelengths. I look forward to seeing the CD-x across the world, the wavelengths and to whatever my next invention may be!