

Interview â?? Osvaldo Carlo, President, Chairman and CEO, ReComS, Puerto Rico



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PharmaBoardroom spoke to Osvaldo Caro, President, Chairman and CEO of ReComS, about the legal side of the pharmaceuticals sector in Puerto Rico.

What are ReComSâ?? defining characteristics?

ReComS is the only company in Puerto Rico that provides consulting services through a combination of attorneys and other professionals. Our staff is divided between technical and legal expertise.

Although we are a small group, ReComS is the only consulting company in Puerto Rico with experience in legal enforcement and within the industry itself. Other companies with similar services in Puerto Rico in this particular area focus solely in the technical area.

Why is that less common? Are professionals in the legal area less interested in this niche?

Corporate law in Puerto Rico allows law firms to establish corporations that can only be comprised of attorneys. Other professionals are not allowed to be involved. The same is true of doctors or engineers. They are Professional Service Corporations (PSC). They cannot enter into competition with us unless they remove PSC, which in their case is very important. ReComS has professionals from different fields that are not involved under a PSC but rather a regular corporation. In the US, some law firms have been able to adopt this combination by recruiting attorneys with technical expertise, which is a very rare breed to find and requires a large pool of professionals for that resource; these are usually individuals who worked as an engineer or chemist in the industry for many years and then became an attorney. Puerto Ricans with such capabilities usually practice on their own or practice with large law firms in the US.

That must provide you lots of competitive advantages over similar companies!

ReComS has been involved with every large case of national impact, such as McNeil and GSK. We have provided our expertise in both Puerto Rico and the US for those companies. The McNeil and GSK investigations were both handled by the federal government. As an attorney with federal practice, you may practice in any state within the Union; however, as most of the substantial facts of both cases happened in Puerto Rico, it was a clear advantage to have someone with local knowledge who also could represent the client in the US.

Where do your clients generally need the most help?

Due to the concentration of life science companies in Puerto Rico, the office of the FDA is very aggressive in their enforcement here. Compared with other jurisdictions with a limited number of pharmaceutical and medical device companies, in terms of geographical area and population, Puerto Rico has substantial presence from the federal government. The government engages in monthly enforcement actions, inspections or auditing of many companies in Puerto Rico. This makes sense given that Puerto Rico produces such a large amount of drugs and devices that are shipped to the US and other jurisdictions. From the security perspective, the DEA is also strongly involved in Puerto Rico.

Indeed, one warning letter can change a company's fortune overnight. Do you help companies with remediation as well?

We do, as well as from the legal side of the regulatory enforcement. We try to remove companies from the possibility of any enforcement actions, civil or criminal. Many consultants are not able to offer services when an investigation turns criminal instead of civil. Once a case becomes criminal, it is referred to a US attorney's office or to the Department of Justice; that requires high-price attorneys to handle the case, because criminal actions can close down operations.

How often are criminal cases associated with malicious intent?

Puerto Rico has never had a case in which the US government has been able to establish malicious intent, but it has been alleged and grand jury investigations have been opened. Companies have had to testify before grand juries. There is not much understanding in the industry of how to protect oneself from what could become a criminal action. Many times it is unintentional. The line is thin between civil and criminal enforcement, and intent is frequently subjective in terms of the approach that prosecutors use. Sometimes information leads to criminal investigations, which can come from dismissed employees who provide information related to alleged illegal actions.

When a criminal action is involved, the penalties are stiff. The two cases that ReComS handled cost one company \$1 billion and the other \$800 million. Many companies are willing to pay those penalties to avoid a criminal trial. But once a criminal investigation is opened, there is an immediate impact on Wall Street. The company's stock suffers because of the investigation and investors respect criminal investigations immensely. It is not only the cost of the legal representation and other penalties, but larger economic costs that are incurred when you are involved as a major corporation.

How do you assess companies' ability to comply? Are they generally aware of what they need to do to avoid such situations?

Comparing Puerto Rico with other US jurisdictions, we have to be at the top in terms of compliance. Locally, Puerto Rico has developed a great deal of expertise. When you have a large concentration of companies as is the case in Puerto Rico, even a couple of cases have national impact. An investigation that is initiated by the FDA would impact a product that is distributed all around the US. There is no small investigation here. Also, many of these large companies operating in Puerto Rico have the federal government as clients, through the Veterans' Administration, whom purchases

medical devices and drugs for US Army and other armed forces. Any legal activity in Puerto Rico can quickly rise to the national level in terms of exposure. That is partly why we must be extra careful here in how we operate. Puerto Rico has a very particular situation compared to other jurisdictions. Beyond the US, Puerto Rico is several decades ahead in terms of enforcement.

One of our areas of business has also been in assisting companies in South America and other regions to obtain FDA authorization to export products to the US. There are many jurisdictions that are interested in getting that authorization, such as Brazil and Mexico, where companies are producing for a US business and therefore must comply with US federal regulations, or non-US companies with an interest in the US market. One of the companies that ReComS assisted in Brazil had veterinary products to introduce to the US, and had to turn around their operation to comply with federal regulations. Europe has a tough regulatory environment as well, so it is easier for that region to comply with FDA standards.

What makes ReComS the preferred partner of choice for regulatory affairs in the industry?

In terms of our knowledge of the business in Puerto Rico, many of ReComS's professionals have decades of experience in the local business in areas of expertise that are frequently used by the industry. We also do lots of work for the local government and we are very involved with local enforcement agencies. ReComS covers both the federal and local sides of the equation in terms of enforcement because operations can be stopped by the local department of health or similar local entities. We combine expertise that in terms of an overview is very general. When you bring an expert from the US, it is limited to the federal field, not the local area, which is also of significant importance.

How did you get involved with ReComS?

I am a former federal US attorney for Puerto Rico and I was in charge of regulatory enforcement against life science companies in Puerto Rico. Much of my career has been spent filing actions against these companies in federal courts. When I left the government in 1996, I immediately received offers from the industry to work as a consultant. At that time, I began an operation providing consulting services for J&J, which operates the largest amount of manufacturing here in Puerto Rico. From then on, I partnered with Eric Olivieri, a J&J Puerto Rico Regulatory Affairs senior leader. He left Janssen in 2003 and we established a partnership under the name of ReComS in the same year. Olivieri passed away in 2006, and thereafter we continued operations with other professionals we had worked with for many years. Verónica Cruz, our executive vice president, came onboard in 2014 from McNeil, having led the J&J affiliate through one of the largest enforcement actions for a consent decree filed by the FDA in the United States.

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