



## CLEARING THE HURDLES!

### LANCASHIRE PARTNERS, LLC.

**Client:** Lancashire Partners, LLC

**Practice Area:** Public Affairs, Public Relations, Strategic Consulting

**Issue:** Regulatory Approval, Market Awareness

**Time Period:** 10-months

**Results:** Defined regulatory process, streamlined regulatory requirements, increased market awareness, developed coalitions and reduced regulatory cost-estimates by \$1.4M

**Campaign Strategy:** Direct Advocacy, Coalition Building, Public Relations,

**Successful Tactics:** An integrated approach that defined the issues, brought clarity to approach while meeting company goals and driving business decisions that reduced overall costs

**Client Profile:** Nanomaterial manufacturer

For new companies with emerging technologies gaining needed regulatory approvals is daunting. For a company with a new antimicrobial technology and who is attempting to complete a “B-Round” capital raise; facing the possibility of multiple regulatory approvals, just to bring the product to the U.S. market, seemed like standing at the base of the Himalayas for a vertical climb with only one rope. EPA-registration requirements, multiple FDA applications, and the USDA were just a few. Internal cost estimates place EPA-registration at \$2M alone with process that spanned well over one year. A clear regulatory process was not outlined by the Agency and at one point two federal Agencies indicated the other had jurisdiction over the approval process. For investors regulatory uncertainty brings higher-risk and longer return-on-investment horizons.

Capitol Core's roll was to define a regulatory process that bought clarity, to streamline areas of that process in order to reduce costs, to organize a timeline that cut ROI-horizons, and raise market-awareness among policy makers as well as industry clients. Further, it was our goal to bring clarity to Lancashire's senior management on which regulatory approval would allow for quicker market access; thus allowing for better business decisions. At the core of our strategy was an integrated approach – well defined issues for a product with multiple uses to span several federal Agencies without causing confusion. Capitol Core brought an “all-hands-on-deck” methodology which used three of the four practice areas within the firm and brought consistency to our message. That message...

*“Lancashire Partners’ product CM-Armor is an antimicrobial substance containing two active ingredients, a common benzalkonium chloride and ammonium calcium-silicate nanomaterial that increases the product’s efficacy between two and 94 hours, depending on the use. The product has multiple uses including (but not limited to) hand sanitizer, food processing facilities, agricultural, and hospital disinfectant. The material stops the surface spread of viruses and microbial materials through a mechanical not chemical kill.”*

#### **PUBLIC AFFAIRS – Regulatory Affairs:**

Our first priority was to work with our federal bureaucracy to increase understanding and define a process (or processes) that made sense for Lancashire Partners.

Several secondary approvals required EPA-registration of the material under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to prove efficacy and environmental issues. For regulators, approval of a new technology with multiple uses is confusing. Capitol Core took a direct advocacy approach working with regulators to increase understanding of the product and materials used to produce the product well before the client would submit an application for registration. We needed regulators to understand the product in order to point us toward the right approval process. Within 40-days, Capitol Core successfully met with regulators, defined a clear regulatory approval process for specific uses of the product, and streamlined needed approvals to reduce timeframes as well as overall costs. Original estimates showed a 14-month process and regulatory costs over \$2M. Our efforts reduced that timeframe to 8-months and below \$500,000 for EPA-registration. Further, it allowed the company to move to obtain other regulatory approval – particularly FDA New Drug Application – on an accelerated timeline.

### **PUBLIC AFFAIRS – Policy-Makers & Thought Leaders**

It is oft said that in highly-regulated environments policies are designed to protect the incumbents. Simultaneous with efforts before federal agencies, Capitol Core briefed Members of the United States Congress and several industry associations with the purpose of raising market awareness and positioning Lancashire Partners as an industry leader in this newly emerging field. This also allowed Capitol Core to block new potential hurdles raised by incumbent competitor companies.

Our Congressional briefings were at the highest levels of majority and minority Members in both Houses. We briefed policy and appropriations committees alike.

Through our industry association meetings, we were able to build strong coalitions for future support requests. It also placed Lancashire's top management in touch with industry thought-leaders that provided invaluable direction and advice. Our coalitions were built through three industries over six associations providing a greater voice for this emerging product.

### **PUBLIC RELATIONS – Maintaining our Supporters**

It is not enough to build a coalition you must care for it and feed its members. Through our standard public relations practices we are able to maximize communications with our partners while minimizing cost-impacts. We communicate regularly with our supporters to tell them where we are on the CM-Armor project, ask their advice, and mobilize THEIR support to tell OUR story in order to meet common goals!

Through our communications efforts Lancashire defines the issues and tells the story – now that's public affairs with strategy at its core!

### **STRATEGIC CONSULTING – Lessening the burden on our Client**

Our strategic consulting efforts took place at the front end and the back-end of this assignment. In the beginning, that was to focus a clear message that built a strong strategic foundation for regulatory approvals. That carried over into marketing messages, investor reports, and even financial offering documents. We combined those efforts with public relations to look for new opportunities, to create sector knowledge and provide clear insights. Our research netted results that built strategic alliances and identified new capital opportunities.

Our secondary strategic consulting efforts were designed to find opportunities for federal, state and private grants that leveraged investor capital and could be applied to lowering the cost of

studies required for EPA-registration and FDA-approval. As the company had limited personnel resources, Capitol Core utilized its knowledge to seek real opportunities rather than “chase money” through grants. We have currently identified two major grant opportunities available to this for-profit small business that can net over \$2M toward meeting its goals.

Through this integrated-approach of public affairs, public relations, and strategic consulting we have brought clarity to a regulatory quagmire, we eliminated hurdles and cleared others with greater ease, we’ve cut the regulatory uncertainty that creates investor-fear, and we’ve defined the issues and told the story to thought leaders and policy makers alike. Capitol Core cut five months and more than \$1M in regulatory costs. The results are strategies and actionable plans with financial accountability **at the core**.