



The **Bruckner** Group, Inc.

STRATEGY & RESEARCH FOR THE PHARMACEUTICAL INDUSTRY

## **Rare Disorder Patients Face Access Restrictions on Expensive Specialty Pharmaceuticals**

### ***Speech Warns of Potential Adverse Changes in Patient Standards of Care***

**Wakefield MA, November 9, 2005.** Rare disorder patients have begun to experience the first negative effects of increasing restrictions on specialty pharmaceuticals by private insurance, according to Michael Russo, Partner at The Bruckner Group, in a speech given at the National Organization of Rare Disorders (NORD) Annual Meeting in October. Michael Russo, a nationally-recognized expert in developing strategic and tactical programs for expensive-to-treat chronic diseases that define, preserve, and maximize access to clinically appropriate standards of care, indicated that if these changes are left unchecked, they could adversely impact patient health status and lead to even costlier problems.

For many people with rare illnesses such as lysosomal storage disease, hemophilia, Guillain-Barre syndrome, and Alpha-1-antitrypsin deficiency disease, specialty pharmaceuticals represent their standard of care, keeping symptoms stable and helping to reclaim quality of life. The majority of insurers and employers have identified these therapies as a cost cutting target regardless of their clinical value. New and re-tooled programs seek to reduce utilization, and a variety of contract initiatives aim to cut reimbursement.

“Bruckner Group research has measured alarming trends,” Michael Russo indicated. “New program design is often dictated not by extensive clinical data incorporating individualized patient needs, but instead by cost targets and a lack of data. This is not sound medicine.” Because of the low prevalence rates of rare diseases, many important clinical events that vary by dosing regimen or brand are unlikely to appear in statistically advantageous numbers. “It is irresponsible at best to set these clinical events aside as anecdotal, and rather attempt to fit patients into a few categories based on commonalities that are statistically measurable,” Michael Russo said. “Within many treatment categories, different brands—varying in manufacturing process and formulation—are mistakenly being categorized as clinically equivalent by default.”

Recognizing the impact of insurance coverage changes on patients, The Bruckner Group has created a tactical plan and a series of programs to proactively protect patient coverage and standards of care. This approach uniquely incorporates the needs of all facets of the healthcare industry, because “without healthy pharma companies and healthy insurance companies, we cannot have healthy patients,” Michael Russo indicated.

**About The Bruckner Group (BGI):**

The Bruckner Group is a strategy and research consulting firm serving the healthcare industry. BGI are the leading experts in developing value-based strategies for pharmaceutical and biotechnology therapies. BGI's proven Outcomes-Based Access framework defines, demonstrates, and leverages the healthcare value of clients' products to build successful product launch and post-launch strategies and tactical programs. BGI's approach creates long-term, defensible competitive advantage by redefining outcomes standards on clients' terms.

**About National Organization of Rare Disorders (NORD):**

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service.