

REGULATORY COMMUNICATIONS

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Preparing the marketplace for the entry of a new drug or device is a process that begins in a product's infancy. This is the period in which misperceptions about a disease can be clarified, low awareness of a condition can be boosted, and issues with current treatment options can be explored – all with the goal of readying the market for the introduction of the new therapy. MCS has managed pre-approval communications for products in nearly every therapeutic category, from a potential cure for the common cold to the first pill for gum disease. We have also supported more than 30 FDA approvals/EU authorizations that have ranged from introducing the first agent in a completely new therapeutic class to announcing line extensions for mature products.

Experience:

- Cardiology: Inspra™, Lovenox®, TNKase™
- Dermatology: Noritate®, Taclonex®, Ulesfia®
- Immunology: Acel-Imune®
- Neurology: Activase®
- Men's Health: Striant®
- Oncology: Erbitux™, Gliadel® Wafer, Novantrone®, Targretin®, Taxotere®
- Over-the-Counter: Nicotrol® OTC switch, ProStep®
- Rheumatology: Enbrel®, Simponi™
- Rare Disorders: Berinert®, Somavert®, RiaStap™
- Women's Health: Detrol® LA

Creativity, Service and Results:

- In support of the approval and launch of Sciele Pharma's head lice treatment Ulesfia®, in collaboration with the National Association of School Nurses, MCS developed and executed a nationwide, multi-media campaign. S.C.R.A.T.C.H. (School & Community Resources to Avoid & Take Control of Head Lice) helped to educate key audiences about head lice and announced the availability of the first non-pesticide treatment option. Campaign messages reached more than 70 million in print outlets such as *USA Today*, *Reader's Digest* and *Parents Magazine*, and through television on *The Doctors*, CNBC and numerous local network affiliates.
- When CSL Behring's RiaSTAP™ for the treatment of congenital fibrinogen deficiency was reviewed by the FDA's Blood Product Advisory Committee, MCS leveraged this opportunity to disseminate key messages and prepare the market and bleeding disorders community for FDA approval of RiaSTAP. Our efforts resulted in original coverage showcasing the positive outcome of the meeting in such outlets as *Reuters*, *Dow Jones* and *Scrip World Pharmaceutical News*.
- In 2003, MCS supported the approval of ImClone Systems' and Bristol-Myers Squibb's Erbitux™ for the treatment of advanced metastatic colorectal cancer. Our video news release, reaching nearly 15 million viewers, and was covered by NBC's Today Show, Lester Holt Live, *Bloomberg News*, and CNN.
- To support the European Commission approval of SIMPONI™, the first and only once-monthly, subcutaneous biologic therapy for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, MCS collaborated with Schering-Plough (now Merck) to distribute an electronic media kit consisting of press materials and a series of physician and patient videos throughout Europe. Materials were translated into local languages and coverage was secured in various pan-European outlets.