



Welcome to the fall edition of "MK&A News," a quarterly e-newsletter designed to familiarize you with our firm's offerings and highlight constituency relations developments of interest to the pharmaceutical, biotechnology, device, and diagnostics industries. We have seen growing interest from patient, consumer, and professional organizations eager to better understand topical health care issues that may impact their constituencies. **We have devoted this edition to global market access issues, with a particular focus on educating and engaging key stakeholders around challenging topics such as health technology assessment (HTA) and comparative effectiveness research (CER).**

At MK&A we are frequently asked by patient groups, "where can we find credible information on CER and HTA?" "How can we let our partners know we care about these topics?" And, most commonly, "what might the future hold?" While we don't have a crystal ball, we can offer tips, suggestions, and insights into what is most important to patients, caregivers, and advocates. Two seasoned MK&A associates offer their wisdom and expertise based on years of experience working with external stakeholders in Europe and the United States around HTA and CER.

Also in this issue, we are delighted to note that our firm is growing, and we invite you to meet the new additions to our staff below.

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**Tackling Health Technology Assessment: The Role of Advocates in Europe**

## About MK&A

MK&A is a health care constituency relations firm that helps pharmaceutical, biotechnology, diagnostics, and medical device companies foster patient, consumer, and professional organization relationships that speed the development, approval, and appropriate use of innovative medical products and services so that all patients have access to the best available treatment options.

## Core Service

- Research and business intelligence
- Strategy
- Patient group relations
- Professional group relations
- Policy influencer outreach

## STAR Report

The STAR Report is a syndicated market research offering from MK&A and The Brooks Group, allowing you to benchmark your company's advocacy relations efforts against your competitors.

STAR 2011 is available now. For more information, [click here](#), or contact Amber Spierer at [aspierer@kruegerandassociates.com](mailto:aspierer@kruegerandassociates.com)

## Quick Links

[Health Equality Europe: A Guide to Understanding HTA for Patients and the Public](#)

[Drug Information Association's Patient Advocacy Fellowship](#)



Health technology assessment is a topic that advocates take seriously because in many countries it plays a significant role in deciding whether or not patients can access specific - often innovative - treatments. [A similar process is in place in the US called comparative effectiveness research; see the article below for more details.] There are numerous definitions

of HTA, but all stress that it is a systematic, robust assessment of the available evidence on the effectiveness of a specific health care technology (always clinical effectiveness, often also cost effectiveness). The evidence that is considered in HTA is usually similar wherever it is carried out, although the decision that is reached about the value of a technology can vary. In large part, this is because the context (i.e. health care setting) in which it is to be used varies.

Patients and patient groups are formally involved in HTA measures in a number of countries, and although by no means universal yet, the inclusion of these stakeholders is increasing. To be effective in representing the patient perspective, patient groups need to understand the processes involved. More than that they need to grasp aspects of pricing and reimbursement, reference pricing, cost effectiveness and even have at least some knowledge of techniques such as Markov models.

When MK&A first started engaging with European groups around their input to HTA measures in 2004, most groups felt that HTA involvement wasn't for them. However, the environment has changed considerably, and now patient groups understand that reimbursement decisions are frequently based on formal - or informal - HTA processes. As a result, training for patient groups in HTA is being delivered in a number of settings. MK&A was at the forefront in this area and developed a toolkit for patient groups on how to contribute to HTA that is freely available on the Health Technology Assessment International website (in English, Spanish, Polish and Mandarin). Many companies contribute financial resources to training programs, and incorporating training in HTA into patient group capacity building activities is one way that they can ensure that stakeholders are "fit for purpose" when they provide evidence for health technology

## [Program](#)

### [1st Annual Rare Diseases/Orphan Products Summit](#)

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*MK&A Managing Director Jean Mossman is based in Europe and is considered an HTA expert, having conducted more than 20 seminars, workshops and trainings on the topic. She has also written extensively on the topic.*

### **Creating Opportunities for U.S. Advocates to Make Their Voice Heard in Comparative Effectiveness Research**

On June 19, 2011, in Chicago, MK&A organized the first Drug Information Association (DIA) US Patient Fellowship Program, which brought together 15 representatives from the cancer



and rare disease communities to learn about and discuss opportunities for their involvement in drug development and health care policy formation, specifically comparative effectiveness research. As comparative effectiveness research is still evolving in the US, patient advocates have a vital role to play to ensure that those they serve have access to optimal care.

MK&A supported the meeting by serving on the steering committee, inviting speakers, and facilitating a portion of a private session focused on advocate involvement in drug development and CER. The session was well received by all in attendance. One participant commented, "I have learned a great deal and now better understand how our organization can get involved in these types of issues to make an impact." Speakers included Marc Boutin, JD, Executive Vice President and Chief Operating Officer of the National Health Council; Ken Getz, MBA, a senior research fellow from the Tufts University Center for Drug Development; Danielle Lavalley, PharmD, PhD, Research Director of the Center for Medical Technology Policy; and James Valentine, MS, Program Analyst of the FDA Office of Special Health Issues.

The Patient Fellowship Program is one of many examples of how MK&A partners with CER stakeholder organizations to incorporate the voices of patients and their advocates in the drug development process and the health care policy arena.

*MK&A President Mark Krueger, MPH, will chair a session at the 1st Annual Rare Diseases/Orphan Products Summit, co-sponsored by the National Organization for Rare Disorders and DIA, on October 12, 2011 entitled "Pathways to Funding of Research: Opportunities for Patient Organizations."*

## MK&A Growth and Opportunities



MK&A welcomes five new associates to its expanding team in New York City:

- *Gary Rose* received his JD from the City University of New York Law School and joins the firm as vice president, bringing 26 years of experience and knowledge in public policy, advocacy, and reimbursement in HIV/AIDS and hepatitis C.
- *Robert Preston* joins the firm as an associate and previously served as manager of international public affairs at Novartis; he holds an MBA from George Washington University.
- *Jeff Fish* and *Aren Kayserian* join MK&A as junior associates. Jeff previously performed translational radiology research at Cornell Medical College, and Aren comes from New York University Langone Medical Center, where he supported medical fundraising initiatives. Aren holds an MSc in social policy and development from the London School of Economics.
- *Shonel Mackie* is the finance team's new billing associate and is responsible for managing revenue and expenses.

Additionally, MK&A proudly announces the following recent promotions: *Ellen Coleman*, senior vice president; *Amber Spierer*, vice president; and *Tamara Montalvo*, finance director.

### **OPPORTUNITY:**

MK&A is currently seeking a vice president to lead its European operations. Interested candidates are encouraged to contact Sarah Shiers of Elektra Partnership, based in the UK, at [sarahshiers@elektrapartnership.com](mailto:sarahshiers@elektrapartnership.com).

### **In Closing...**

We welcome the opportunity to apply our firm's knowledge and

expertise in patient, consumer and professional relations to helping you achieve your goals.

Let us know how we can assist you by calling us at + 1 212 620 2770 or e-mailing us at: [mkrueger@kruegerandassociates.com](mailto:mkrueger@kruegerandassociates.com).

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