STUDENT CORNER Neha Patel

A patient-centered approach

Drugs marketed in the United States are directed for specific use in patients. The beneficial or adverse effects of the drug directly impact the patient. Therefore, it is vital to understand the patient's perspective at various points throughout the drug approval process. Patients can serve as checkpoints to guide drug development down the most efficient path.

The increasing value of patient perspectives suggests the evolving outlook on the drug approval process. Patients are now seen as invaluable resources in expressing the reality of a drug. They weigh risks and benefits, and then offer a perspective that is beyond the vision of drug developers. This has encouraged patients to be the voice of those who can't speak and to compel decision-makers to listen. What was once thought to be a rigidly organized approval process now has avenues through which it seeks and integrates public comments at a greater level.

Patients voice their opinions

FDA has various programs to assure that patient participation is incorporated into its decisions, such as the Drug Development Patient Consultant Program (DDPCP), and the Patient Representative Program (PRP).

FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research offer patients with serious illnesses an opportunity to contribute their thoughts, including during meetings between FDA and pharmaceutical manufacturers in the DDPCP. These patients offer feedback concerning clinical, legal, and regulatory matters. And the PRP allows patients who have personal experience managing a condition to express their issues and concerns.

The role of patient reps

Patient representatives are responsible for providing FDA with this unique perspective on serious or life-threatening conditions.

Patient reps serve as voting or nonvoting members on advisory committees while actively communicating concerns related to the product under review. The goal is to aid FDA in making reliable assessments regarding the safety, effectiveness, and appropriate use of the product.

Active involvement in advisory committees encourages public interaction with FDA as it arrives at conclusions. President Obama's dedication to allowing public access to the government spurred the U.S. Department of Health and Human Services to open its proceedings to the public. As a result, FDA Commissioner Margaret Hamburg, MD, introduced a Transparency Initiative in June 2009. Part of the initiative focuses on assimilating public feedback to modifiy the agency's mechanism. The structured patient advocacy programs are taking FDA closer to achieving its transparency goal.

Training, viewpoints

Patient reps are trained prior to their advisory committee meeting and are well informed about FDA's deliberation process. The bulk of the training occurs in an annual 2-day Patient Representative Workshop hosted by FDA's Office of Special Health Issues (OSHI). Reps also receive education and information through one-on-one discussions with OSHI staff, webinars, and bi-weekly electronic newsletters.

At the 2011 Patient Representative Workshop, patient reps shared their views of their involvement in the deliberation.

Taking initiative in one's own healthcare is "critical," said Phillip Posner, a new patient rep. "Patient representatives can steer FDA in the most efficient direction while affirming or rejecting the realistic acceptability of a drug candidate."

Susan Krivacic, a long-time patient rep, said, "The patients are the real deal. They are the ones who highlight the cultural, social, and economic issues that affect data integrity and, therefore, best represent the target audience."

Patient reps are skeptical about "the conventional wisdom regarding a drug, which can expose drug issues that were previously overlooked," new rep Elizabeth Smith said. Patients have a chance to express safety and quality concerns in the truest essence, having had an experience that might not resemble the textbook definition of the condition.

The more patients become involved and informed, the more they can participate actively in their healthcare, and, subsequently, the better informed FDA's drug evaluation process will be. Essentially, it is the "moral duty [of patients to] assert their autonomy during the drug development process," Krivacic said.

Ultimately, public participation is necessary to achieve satisfaction both by those involved in the approval process and by users of the end product. DT

Neha Patel *is currently a second-year pharmacy student at the University of Maryland School of Pharmacy. Dr. Helene Clayton-Jeter works with the Patient Liaison Program in FDA's Office of Special Health Issues.*

ADVANSTAR MEDICAL COMMUNICATIONS GROUP
Reprint Rights Only. All Rights Reserved. Copyright Advanstar Communications Inc.