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Dr. Li received his Doctor of Pharmacy from the University of the Sciences in Philadelphia. He completed a pharmacy practice residency at the University of Wisconsin Hospital and Clinics and an Oncology Pharmacy Practice Residency at the University of Maryland School of Pharmacy. Before joining NCCN, Dr. Li was an Assistant Professor of Pharmacy Practice at Wilkes University. His research interests include the development of a paradigm to incorporate comparative effectiveness judgments into practice guidance, and quality assessment/improvement initiatives.

The ideas and viewpoints expressed in this commentary are those of the author and do not necessarily represent any policy, position, or program of the NCCN.

Exploring Pharmacy and Drug Policy Concerns

JNCCN—The Journal of the National Comprehensive Cancer Network, Special Edition: NCCN Oncology Pharmacy & Policy is a new, special edition of *JNCCN* that focuses primarily on issues related to pharmacy and drug policy in the United States. Increasingly, the oncology practitioner must keep abreast of not only the clinical but also the regulatory aspects of oncology care. These regulations have the potential to significantly impact practitioner workload and how care is delivered to people with cancer. *JNCCN Special Edition: NCCN Oncology Pharmacy & Policy* provides viewpoints on and a forum to discuss these issues. For example, this first issue focuses on a subject currently being discussed at the national level and likely to extensively affect hospitals and oncology practices: Risk Evaluation and Mitigation Strategies (REMS).

A few years ago, I received a call from my mother—also a pharmacist—who works for a pharmacy that provides services to long-term care facilities. She was requesting a crash course in interpreting and calculating a patient's absolute neutrophil count (ANC). The FDA had just required ANC as a parameter for monitoring patients on clozapine therapy, and she was in charge of monitoring and reporting the required information to the Clozaril National Registry for the approximately 200 patients in her pharmacy taking the drug. A couple of things struck me. First, I was surprised that a significant portion of my mother's time (~ 2 hours a day) was dedicated to monitoring these patients without being given specific time by her employer to conduct these tasks. Second, I shuddered at imagining a scenario where I would be statutorily required to submit my oncology patients' ANC data to a registry. "Better you than me," I jokingly said at the time. This was my first exposure to the challenges of REMS but certainly not the last.

Signed into law on September 27, 2007, and effective on March 25, 2008, the Food and Drug Administration Amendments Act of 2007 gave the FDA "enhanced authorities regarding postmarket safety of drugs." This allowed the FDA to require REMS for drugs that carry a high risk potential. Some drugs, including clozapine, already had a "Risk Minimization Action Plan" in effect, and these were grandfathered under the REMS umbrella.

Although reporting patients' ANC values to a central data repository for traditional cytotoxic chemotherapy probably won't be required under the REMS program, REMS is likely to significantly impact oncology practice nonetheless. For example, about half the agents with elements to assure safe use listed on the FDA's Web site of approved REMS are prescribed by oncologists and hematologists. Just as my mother spends a significant portion of time dealing with regulatory requirements for one drug, there is concern about the time oncology providers will need to meet REMS requirements, especially since the question of whether these programs actually increase safety remains unanswered.

To address issues such as provider workload and whether REMS increases patient safety, NCCN convened a Work Group to determine recommendations for various stakeholders, including the FDA. This Special Edition presents the resulting NCCN Risk Evaluation and Mitigation Strategies White Paper, which contains not only these recommendations but also data from a recent NCCN survey regarding REMS in clinical practice.

However, REMS is not the only critical issue. In addition to departments such as Policy in Practice, this edition contains reports on 2 other important matters. First, an update to the 2009 NCCN Insights Report: Managed Care & Medical Oncology—Cancer Is Now on the Table reflects interviews with executives from 10 managed care organizations about the future of managing oncology care. Second, a report discussing

the clinical and operational challenges related to the management of cancer-related anemia details an NCCN Member Institution's initiative to reduce the use of blood products and also includes results from 3 different NCCN surveys on this controversial topic.

As a pharmacist, I am excited to be part of the first *JNCCN Special Edition: NCCN Oncology Pharmacy & Policy* and look forward to future issues, which will feature clinical case reports and literature review along with other white papers and policy reports. We hope that you will find this information useful for your daily practice.