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Oral Testimony Given by Karen Hagerty, on behalf of the American Society of Clinical Oncology

Risk Evaluation and Mitigation Strategies Public Meeting

Docket Nos. FDA2010N0284 and FDA2009D0461

My name is Karen Hagerty, and I am here today representing the Chief Executive Officer of the American Society of Clinical Oncology (ASCO), Dr. Allen Lichter. I am here to present remarks on behalf of the more than 27,000 members of our society. ASCO is the world's leading professional organization representing physicians who treat people with cancer. We support the FDA's efforts to improve drug safety and are pleased that the agency has shown a willingness to reach out to the community for input on its REMS program. We offer both our comments and our assistance in building sound drug safety policy.

The challenges facing physician practices today are many, including the rapidly expanding administrative requirements to demonstrate value, quality, regulatory compliance—and patient safety. In some cases, the resources required to manage this aspect of practice—across multiple payers and agencies—has begun to outstrip the resources employed in the actual care of patients. An oncology practice implements a team-based approach utilizing a broad range of healthcare professionals to build quality and safety into practice as opposed to a layering approach, an often unintended consequence of regulation. REMS programs, if designed appropriately, can provide additional benefit to physicians and patients where drug safety issues are a concern. However, it is important for the agency to understand current quality and safety standards that are already in place to ensure that REMS programs do not disrupt practice tools that are already working such as the Quality Practice Oncology Initiative (QOPI). We need to bridge the knowledge gap between practice and regulatory science so that we can best meet the needs of our patients.

Of the approximately one hundred REMS currently in existence, only a few make use of all of their potential elements, including restricted distribution under elements to assure safe use. These few REMS cover drugs that

oncologists and hematologists routinely prescribe, so we feel their impact in our day-to-day practice. FDA should focus REMS on drugs with side effects that are an anomaly to those who would prescribe them...not just because the safety profile has toxic side effects. As oncologists, we face daily the challenge of balancing patient safety against the need to employ extremely toxic treatments with narrow therapeutic windows used to treat an array of life-threatening diseases. We understand how to implement the appropriate processes and safeguards to ensure patient safety for oncology drugs on the market today and are well-versed in having these discussions with our patients. We also understand that future drugs may have uncommon side effects outside of the standard practice of oncology. Therefore, it is important that we work together to develop REMS that focus on these unusual side effects to ensure that important safety issues are not obfuscated by blanket drug safety programs.

Metrics are extremely important. The only people who lose if we don't do this right the first time are our patients. Therefore, the agency needs to ensure that the programs are designed to and assessed against improving patient safety. Checking a box doesn't necessarily result in improvements for our patients and may actually interfere with our goals of improving safety outcomes.

We recognize that legislation puts the responsibility for developing REMS on the sponsors. However, we continue to feel that, for those REMS requiring physician and patient education, it is more appropriate to utilize the educational resources of professional organizations, including the use of existing mechanisms for delivering accredited CME.

We would like to work with the agency to develop drug safety principles in oncology to ensure when these drugs with new safety signals are approved, oncologists are armed with the knowledge of their safe use. Emerging science coupled with practical tips for safe use is an important partnering of information. Our long experience in promoting new science, implementing quality practice initiatives and developing oncology education can offer unique insight as the FDA moves to strengthen the process and outcomes of its REMS program. We have enjoyed a strong partnership with the FDA and look forward to continued collaboration and open dialogue as we work towards assuring patient safety and the highest quality care.