Conflict of Interest and Oncology Guidelines

“There is no greater threat to the integrity of the clinical research enterprise than the appearance or reality of a conflict of interest—be it financial, academic, or scientific.” This is from the American Society for Clinical Oncology (ASCO) guideline on oversight of clinical research, and it would seem to apply also for the NCCN guidelines, which are created by experts from leading academic oncology centers and built on results of research and clinical judgment.

Public scrutiny of conflict of interest in medicine is at an all-time high, fueled by expanding concerns over relationships between industry and physicians and ignited by reports of abuses. Ethicists note that conflict of interest rules are designed to maintain the “integrity of professional judgment” and to “minimize conditions” that would cause others to question that judgment.1-5 Rules center on disclosing, managing, and, when necessary, prohibiting conflicts. Yet research studies have shown tremendously variable practices, including how conflicts are classified and reported, monetary values permitted, and the management of potential conflicts.3,4

Greater transparency in conflict of interest management is important. In response to these evolving concerns, NCCN recently revised its conflict of interest practices (http://www.nccn.org/about/disclosure.asp). Instead of reporting the entire panel membership conflicts as an aggregate statement, NCCN has begun reporting individual disclosures for each panel member. Other oncology organizations, such as ASCO, are also revising conflict of interest policies for individuals on guideline committees.

Furthermore, these steps are only part of a growing roster of probable changes in how potential conflicts are reported and managed. Several long-accepted practices are being challenged. For example, voluntary reporting has been questioned, because of instances of substantial gaps between self- and industry-reported claims and of fraudulent underreporting. Several pharmaceutical companies have announced the intent to publish lists of clinicians with whom they have relationships, and calls have been made on Capitol Hill for legislation to require such reporting.

Calls have also been made for the quantitative reporting of dollar values. Of course, specific thresholds for conflict are, by nature, arbitrary, and they fail to acknowledge that different numbers mean different things to various individuals. De minimis cutoffs may seem “trifling” to some individuals; well-paid relationships might more substantially impair independent judgment or create the impression of it.

Finally, recognition that non-industry relationships, too, can create conflicts is increasing. For instance, clinicians with practice incentives aligned to specific drug or treatment modalities have direct conflicts, though these are usually thought to be “aligned” with the needs of patients.

The challenge for leading academic cancer centers and investigators is to maintain relationships with pharmaceutical and commercial entities—relationships that have proven essential for progress in oncology and other clinical disciplines—without compromising their role as clinicians and scholars.3 At present, industry accounts for most commercial innovation in therapeutics and diagnostics in oncology, creating a vital pipeline of drugs and products that help cancer patients. It is time for creative thinking on how to foster such relationships in ways that serve all constituencies—academic clinicians, patients, and industry sponsors—with transparency, integrity and innovation. Organizations like NCCN, built on the collective input of comprehensive oncology centers, have the opportunity and obligation to think imaginatively about ways to engage with industry, generate fertile interchange between academic centers and industry, and manage conflicts in a more constructive fashion.

References