Chapter 4. Conclusions

With regard to the two best-case series, our review supports the following conclusions:

- The IAT cases provide sufficient indications for the recommendation that IAT warrants further study.

- The Naltrexone cases provide insufficient indications to determine the likely benefit for Naltrexone at this time.

For IAT, this review suggests there is sufficient evidence to recommend that a random controlled trial could be considered. For Naltrexone, a prospective cohort case series should be considered.

Limitations of the Study

This study suffers from several limitations. First, as noted earlier, a best-case series is inherently a weak form of evidence to draw conclusions about a cause-and-effect relationship. Secondly, we encountered several difficulties trying to establish a best-case series. While the cooperation of the two clinics and patients was excellent, problems we encountered include the following:

1. *The quality of the records.* Because the study involved retrospective analysis of existing patient files, the records were not constructed with the view that they would be used for research studies. They were frequently incomplete and, as shown by the patient interview, on occasion incorrect. In many instances, the research team was unable to abstract the needed information from the files.

2. *Confirmation.* An essential component of the NCI best-case series is confirmation, both pathological and/or visual, of the diagnosis, the history of the cancer, and the outcomes. Most patients were willing to give consent for us to obtain the necessary information (pathological tissue samples, slides, x-rays, etc.), and the institutions were willing to deliver it. However, for the most part, these crucial pieces of evidence no longer existed. While long-term survival is an important outcome, it complicates the collection of data because most institutions do not keep pathological tissue and/or radiographic films beyond five years.

3. *Documentation of treatment*. Many of the patients experienced a long period of various conventional treatments, and a smaller group of patients underwent a variety of CAM therapies. When the treatment chronology cannot be clearly documented and/or confirmed by the patient, it becomes impossible to attribute an outcome to any particular therapy. An additional problem is that once the CAM therapy starts, the documentation of other (usually conventional) care largely ceases. Furthermore, the CAM therapy itself is often not clearly documented.

4. *Self-selection.* Individuals who choose to attend a CAM clinic do so through a self-selection process. Related to this issue is the potential role of patients' belief systems in the healing process.

5. *Multi-care*. The patients whose cases we reviewed tended to use multiple treatment methods. In addition to receiving a CAM therapy, most had also received conventional care (although in some instances they had refused such care). Frequently, the patients had also employed a range of alternative therapies. In these cases, pinpointing the therapy that might have led to a particular outcome is impossible.