Dear Dr. McCarthy:

"Managed care" ostensibly promotes the use of evidence to optimize medical care. Unfortunately, guidelines and requirements can stifle physicians in their attempts to provide patients with high-quality medical care. The availability of effective oral antifungal medications for onychomycosis offers new opportunities for treatment and new challenges for funding the cost of medical treatment. The article by Mehregan and Gee (The cost effectiveness of testing for onychomycosis versus empiric treatment of onychosdystrophies with oral antifungal agents, *Cutis* 64: 407-410, 1999) provides important information that could be useful to clinicians needing data to support their use of fungal cultures in the management of onychomycosis. The scope of the conclusions drawn by the authors, however, could be used to establish an unwarranted standard requiring the use of such cultures.

The conclusions of the author, "it is more cost effective to first confirm the diagnosis of onychomycosis and then treat only those with infection," is not fully supported by the methodology of their investigation. The study only included specimens that clinicians chose to send to the laboratory for investigation. There may be many instances in which clinicians choose to treat onychomycosis based on characteristic clinical findings alone (laboratory studies were only done at about 50% of new patient visits for onychomycosis according to 1996-7 data from the National Ambulatory Medical Care Survey). Since such samples were not included in the analysis, the study findings should not be generalized to such cases. A more limited and appropriate conclusion for the manuscript would be, "when clinicians feel a fungal culture is warranted in the treatment of onychomycosis, it is cost effective to obtain this laboratory study." Another important limitation of the study that must be considered is the false-negative rate for fungal cultures in the diagnosis of onychomycosis. The authors point out that diagnostic accuracy with culture may be as low as 50 to 70%. A sensitivity analysis was not included in the calculation of cost effectiveness in this study. In this study, 35% of the samples had negative results, so if the false-negative rate was 35%, all the patients actually did have onychomycosis. As the false-negative rate is likely due to inadequate sampling more than any other factor, positive results with a positive control sample in the laboratory cannot rule out a false-negative clinical result.

From the perspective of the clinician, the possibility of false-negative culture results raises the concern that the "costs" of not treating patients who actually do have treatable onychomycosis was not considered. If the false-negative rate accounts for the negative results, requiring a fungal culture might save money, but it would not be "cost effective."

Sincerely, Steven R. Feldman, M.D., Ph.D. Director of Westwood Squibb Center For Dermatology Research

Alan B. Fleischer, Jr., M.D Co-Director and Associate Professor

Dr. Darius R. Mehregan replies:

While it is true that we studied only specimens that clinicians chose to send for investigation, these clinicians did not make arbitrary decisions on which specimens to send and which patients to treat empirically. All of these specimens were from physicians who were in the practice of testing all patients prior to treatment for oral antifungals. Therefore, there was no physician selection bias among the patients studied.

While I may also concede that dermatologists would on the average be able to make a more informed decision as to who should be tested and who should not, this medicine has widespread usage among family practitioners and internists. Physicians in all specialties have been subjected to the marketing of these medications, and patients often go first to their primary care physicians specifically for treatment for dystrophic nails with oral antifungals.

The authors point out that our diagnostic accuracy with culture may be as low as 50 to 70%. However, we did not use fungal cultures; we used nail biopsy specimens. In a study by ourselves and another study by Dr. Baran, nail biopsies were shown to have a greater sensitivity than nail cultures.

I agree with the letter writer that guidelines are often helpful, but can be used to establish unwarranted or restrictive standards of care. However, I believe that many of our primary care and internal medicine readers find such guidelines to be helpful. *Cutis* is certainly an appropriate journal to have such discussions regarding the use of guidelines in medicine.