



# American Chinese Pharmaceutical Association Newsletter

美洲華人藥學會通訊

Editor: James W. Shaw, Pharm.D., M.S.

June 2003

## Message from the President Jonas Wang, Ph.D.

My dear ACPA fellows, I hope that you had a wonderful and relaxing Memorial Day Weekend. During the second quarter of 2003, the ACPA Executive Committee made several important decisions that I would like to share with you.

The 6th ACPA International Conference and Workshop, which was originally scheduled for August 1-3, 2003 in Taipei, Republic of China, has been postponed until early spring 2004 due to the spread of Severe Acute Respiratory Syndrome (SARS) in Asia. The Executive Committee has restated its strong support for this conference in the belief that it will allow ACPA members living in the U.S. to share knowledge and technology with members living overseas and will enhance professional relationships between the two continents. Ergo, the conference will be jointly held with the 50th anniversary celebration of the National Taiwan University School of Pharmacy as originally planned. We encourage every member of ACPA in the U.S. and Asia to try his or her best to attend this important event. Since the conference will be held in 2004, the Association's President-Elect, Dr. Wendy Chou, will assume responsibility for hosting the conference.

I would also like to inform you of two key conferences that have been scheduled for our members. ACPA will co-sponsor a meeting titled "Bio/Pharm 2003 - Opportunities Across the Asia Pacific," which will be held September 19-20, 2003 at the Radisson Valley Forge Hotel in King of Prussia, Pennsylvania. This conference will present a forum for researchers and entrepreneurs to interact with venture capitalists and government funding officers from Taiwan and the U.S. This two-day conference will facilitate the formation of partnerships, which are critical for the advancement of the biopharmaceutical industry. It is hoped this event will serve as a catalyst for entrepreneurs, researchers, government officials, and venture capitalists to advance their visions, ideas, and technologies. A registration form for the meeting is included with this issue of the newsletter. For more information, interested members are encouraged to visit the SCBA web site at <http://BioPharm.us>. ACPA will also

sponsor a mini-seminar at the AAPS 2003 Annual Meeting and Exposition, which will be held October 26-30, 2003 at the Salt Palace Convention Center in Salt Lake City, UT. The mini-seminar has been scheduled for the evening of Tuesday, October 28, 2003. The identity of the keynote speaker will be announced in the next issue of the newsletter.

Under the strong leadership of the Executive Committee, ACPA is now updating its web site and membership directory. We are also planning strong efforts to recruit new members to our organization. It is important for all of us to help build the Association and make it stronger so that it may better serve its members in both the U.S. and Asia. We welcome your comments and suggestions and appreciate your support. If you have any ideas that you would like to share with us, please feel free to contact me either by e-mail at [jwang@sycamorevc.com](mailto:jwang@sycamorevc.com) or by telephone at (609) 759-8888. Thanks.

## Message from the President-Elect Wen-Hwei (Wendy) Chou, Pharm.D., Ph.D.

I would like to take this opportunity to extend my sincere appreciation to all of you for giving me the great privilege to serve as President of ACPA in 2004. I look forward to continuing our Association's efforts to create and advance opportunities within the pharmaceutical profession for those of Chinese heritage. Currently, I work very closely with our President, Dr. Jonas Wang, and all the Executive Committee members. I have come to the realization that our Association's success relies on the volunteerism, commitment, enthusiasm, and dedication of its leadership and, most importantly, on the support received from its members. I urge you to continue to support our organization and its programs. Working together as a team, I believe that we can achieve our personal, professional, and societal goals. In order to serve you better, I would like to hear from you. Please send me your comments, suggestions, and any specific goals that you would like for us to achieve during the upcoming year. My email address is [chouw@cder.fda.gov](mailto:chouw@cder.fda.gov). Thank you.

## Meeting Announcement

The Bio/Pharm 2003 Conference, which was originally scheduled to be held on June 20-21, 2003 at the Newark Marriott Hotel in New Jersey, has been rescheduled due to concerns over the outbreak of SARS in the Asia-Pacific region. We apologize for any inconvenience this may cause our members. However, we believe this is the most prudent action at this time. We ask our members to distribute this information to all those who have planned to come to this meeting. The new date for the Bio/Pharm 2003 Conference is September 19-20, 2003. The conference is now scheduled to be held at the Radisson Valley Forge Hotel in King of Prussia, Pennsylvania.

Thank you very much for your support and enthusiasm for the Bio/Pharm 2003 Conference. Please feel free to contact Jonas Wang, Ph.D. at [jwang@sycamorevc.com](mailto:jwang@sycamorevc.com) if you have any questions about this meeting. We look forward to seeing you in September!

## ACPA Membership Directory

ACPA is in the process of updating its membership directory. At this time, we intend to e-mail the directory to members in a Microsoft Excel file. The directory will include each member's name, job title, place of employment, office phone number, and e-mail address. If you have recently moved or changed jobs and would like to have your current information appear in the directory, please contact Chester Lau by telephone at (609) 394-4236 or by e-mail at [clau@chsnj.org](mailto:clau@chsnj.org) on or before July 11. The directory will be sent to all active members by the end of July.

We request that those with Hotmail accounts ensure that adequate space will be available for them to receive the Excel file by e-mail. We have no plans for mailing hard copies of the directory to members at this time. However, requests for hard copies will be considered on an individual basis.

## Onychomycosis: Health-Related Quality of Life Considerations James W. Shaw, Pharm.D., M.S.

The following article is re-printed from *Topical News in Onychomycosis*.

### 1. What factors are patients most concerned with in the perception of their own health?

Patients desire (1) to live as long as possible; (2) to function

normally; (3) to be free of pain and physical discomfort; (4) to be happy, free of stress, and in control of their emotions; (5) to maintain the social relationships that they are accustomed to; and (5) to remain in material/financial health after attending to their medical expenses.<sup>1</sup> Thus, the health-related dimensions that are most salient when measuring patient quality of life include functioning, pain, and emotional well-being. Social relationships and material well-being are also important, though these may be construed as being independent domains as opposed to subdomains of health. To the extent that disease symptoms or a treatment's clinical benefits or side effects impact these areas of life, one would expect patient quality of life to be affected.

### 2. Which symptoms of onychomycosis most influence patients' perception of health?

These include difficulty in cutting nails; limitations in the types of footwear that may be worn; thickening, splitting, and discoloration of affected nails; and pain/discomfort.<sup>2-6</sup> The domains of life that appear to be most affected by onychomycosis include social interactions, physical functioning, and pain. In addition, reduced self-esteem resulting from nail appearance may result in feelings of anxiety or unhappiness, yielding diminished emotional well-being.<sup>7-9</sup>

### 3. Is the effect of onychomycosis greater on psychosocial or physical functioning?

It is difficult to state with any degree of certainty whether physical or psychosocial domains are more affected by onychomycosis. The effects of physical symptoms and functional limitations appear to be somewhat stronger than the effects of reduced social or emotional well-being. However, future studies should seek to determine the relative importance of physical and psychosocial domains when measuring quality of life in patients with onychomycosis.

### 4. Which assessment tools are available to examine the impact of onychomycosis, and its treatment, on health-related quality of life (HR-QOL)?

There are a number of instruments that have been developed to assess the impact of onychomycosis on patient quality of life. The most important of these include an onychomycosis questionnaire developed by Lubeck et al.,<sup>7,8,10-12</sup> a questionnaire designed for multinational studies developed by Drake et al.,<sup>13</sup> and the Onychomycosis Disease-Specific Questionnaire (ODSQ).<sup>9</sup> Other disease-specific instruments have also been developed by Whittam and Hay,<sup>3</sup> Elewski,<sup>4</sup> and Drake et al.,<sup>2</sup> however, there is limited information regarding the psychometric properties of these tools.

### 5. How do these tools differ and what information can they provide?

The three assessment tools for measuring quality of life in onychomycosis patients that have undergone some degree of validation appear to have distinct advantages relative to one

another. Of the three instruments, the Lubeck et al. questionnaire appears to be the most responsive to clinically meaningful changes in disease status over time. The international onychomycosis-specific quality of life questionnaire developed by Drake et al. is the only measure available in languages other than American English. In addition, among the three major assessment tools, the Drake et al. questionnaire is the only one for which a comprehensive fingernail-specific version exists.

The Lubeck et al. questionnaire and ODSQ include more comprehensive sets of scales than the Drake et al. measure. Both include disease-specific scales measuring the impact of nail appearance and functional limitations on quality of life. The ODSQ includes disease-specific scales measuring social well-being, the inconvenience of foot care, and pain. However, both questionnaires include generic scales measuring pain and social functioning. Distinct from the ODSQ, the Lubeck et al. questionnaire includes a number of scales measuring the frequency and bothersomeness of toenail symptoms as well as a scale that measures satisfaction with treatment.

#### **6. What are the potential limitations of these questionnaires?**

The Lubeck et al. questionnaire has not been validated for use with patients who have fingernail disease. The version of the instrument that is discussed in several sources is effectively toenail-specific and should be used only in patients with toenail disease. Similarly, the published version of the ODSQ excludes fingernail-specific items and is suitable for use in patients with toenail disease. Information pertaining to the responsiveness of the scales of the Drake et al. questionnaire is lacking. This is an important consideration if one wishes to assess changes in quality of life over time. The Drake et al. questionnaire should be used cautiously in evaluative studies.

Each of the three major instruments includes a number of generic quality-of-life scales derived from other questionnaires. In general, these scales have been found to be less sensitive than the disease-specific scales to differences between groups and unresponsive to clinical changes occurring in onychomycosis patients over time. In spite of these concerns, there may be situations in which the generic scales provide valuable information. Generic measures permit comparisons across interventions and diagnostic conditions and allow dysfunction to be quantified for an individual experiencing several disease conditions at once.

#### **7. Have any such questionnaires been used clinical trials?**

To my knowledge, of the three major instruments available for use in patients with onychomycosis, only the ODSQ has been used in a clinical trial. The ODSQ was used in a clinical trial comparing oral antifungal therapy with placebo.<sup>9</sup> While quality-of-life differences between treatment and placebo groups were not assessed, the published findings were suggestive of a positive association between treatment

efficacy and quality of life. Patients with unresolved disease had significantly lower scores than cured or improved patients on most of the ODSQ's disease-targeted scales. In addition, patients who demonstrated a mycological cure (as evidenced by a fungal culture that was negative for dermatophytes at the end of therapy) had significantly higher scores than patients with persistent fungal infection on the instrument's disease-targeted scales.

#### **8. Which areas should future investigations of available questionnaires concentrate on?**

Future investigations using the available questionnaires should seek to evaluate the impact of onychomycosis treatment on patient quality of life. As it stands, there is little information in the existing peer-reviewed literature concerning the effect of treatment on patients' functioning and well-being. In particular, studies comparing the effects of alternative treatment modalities (i.e., head-to-head comparisons of medications or comparisons of pharmaceutical and surgical interventions) are warranted.

#### **9. How can we improve our understanding of the impact of onychomycosis treatment on patient HR-QOL?**

Borrowing from Campbell et al.<sup>14,15</sup> and others, I think we need to focus more on the effects of onychomycosis and its treatment on individuals' subjective well-being. With the exception of Lubeck et al., few investigators have sought to evaluate the extent to which onychomycosis treatment affects individuals' satisfaction or happiness with individual domains of life or with life in general. I believe that it would be instructive to develop a broader picture of how onychomycosis treatment may influence satisfaction with health and how this may affect satisfaction with other domains (e.g., work, marriage). Further, we should seek to identify the reference standards that individuals use when evaluating the perceived effects of treatment. For instance, do individuals compare their current level of functioning to that of their peers, to their perceived needs, or to their goals and aspirations? With the exception of the work of Michalos,<sup>16</sup> there has been very little research in this area to date.

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