

Consumer Healthcare Products Association

CHPA Chairman's Address and President's Report*

CHPA Annual Executive Conference

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Turnberry Isle Resort & Club

Aventura, Florida

Following is a summary of the report given by CHPA Chairman Richard K. Green, president and chief operating officer, Blistex Inc., and CHPA President Linda A. Suydam, D.P.A., at the Association's 2003 Annual Executive Conference in Aventura, Florida. The session, which took place during the meeting's March 15 Second General Session, was moderated by Catherine A. Sohn, Pharm.D., vice president, worldwide business development, GlaxoSmithKline Consumer Healthcare Worldwide:

Sohn: Good morning everyone and welcome to the Chairman and President's session of the AEC. Welcome Dick and Linda and thank you for being here today.

Green and Suydam: Thank you.

Sohn: Dick, I know that you are a long-time member of CHPA, but what can you tell us about your first year as the Association's Chairman?

Green: Sure, it was a piece of cake. While I would have preferred serving as the Association's Chairman-Elect for a year before I took over the Chairmanship, it certainly wasn't the blind leading the blind as we had thought. I think we really challenged ourselves this year and I have had great support from an excellent Executive Committee and Board of Directors.

Sohn: Linda, you've been on board as CHPA's President for nine months after a long and impressive career with FDA. How does it feel sitting on the other end of the table now?

Suydam: It feels great. While it's been challenging, it's also been rewarding and I was surprised at how easy the transition was. Early on the member visits helped me to understand the industry better as well as to get to know members and they, me. It was extremely beneficial.

Sohn: Dick, in addition to welcoming some new senior staff to the Association, CHPA has implemented several new initiatives this past year. Could you tell us about a few?

Green: Sure, but the first item I'd like to mention, while not necessarily new, is something that I think we do very well — our new member orientation. I attended one in January and I have to tell you, I really learned a lot. CHPA truly is a member-driven

*The Bylaws of the Association provide that the President shall give an annual report to the membership. The 2003 President's Report was given in a Q&A format, along with the Chairman's Address. This text is the basis of the oral presentation. It should be used with the understanding that some material may have been added or omitted during presentation.

Association. As far as what's new — in the past year we have reviewed and reassessed staff duties and responsibilities and assigned the people to the right jobs. And under Linda's charge, the CHPA office space is much cleaner and more organized. In addition, CHPA has placed an even greater emphasis on the needs of its members. For example, the Association recently formed a new Logistics Steering Committee. We've also added a new event called "CHPA MarketPlace" to our calendar of regular meetings.

Sohn: Linda, Dick mentioned a CHPA MarketPlace event. What exactly is it?

Suydam: After last years Annual Executive Conference we had a reinvention committee to look at this meeting. They decided that the member/business appointments were so successful that we should devote an entire meeting to the process. This will provide our Associate members with more face time with our active members and with more members of their teams. September 18th is the date in New Jersey, so mark your calendars.

Green: I would like to add to that if I may. This provides all of us with great opportunity to send so many more of our people. CHPA MarketPlace gives our Associate members the chance to show off their new and existing products and services. The entire Board of Directors, including myself, is committed to sending our appropriate staff to CHPA MarketPlace to make certain this new event is a big success. And we are also guaranteeing at least seven appointments for Association members that participate.

Sohn: Linda, I understand that CHPA recently hired a vice president of corporate development and a new vice president for communications and strategic initiatives. How do these changes fit in with your overall goals for CHPA?

Suydam: My goal was to make CHPA a more efficient and effective organization with member needs being paramount. After some external analysis we streamlined the organization – downsizing about six positions, but at the same time we had major needs to meet. So I've brought Ted Peterson on board to not only manage member recruitment and retention activities but to identify new streams of revenue for the association. Virginia Cox's position is redefined from a straight Public Relations focus to look more strategically at how we communicate and engage allies more effectively.

Sohn: Linda, you've mentioned CHPA's mission and priorities for the future. What exactly are the Association's priorities?

Suydam: At last year's annual meeting, the Board identified five top priorities for the Association. The first is enhancing relationships with FDA. The second is developing and promoting the benefits of OTCs and dietary supplement products in the overall healthcare system. The third is building the environment for Rx-to-OTC switch, something that Dr. McClellan touched on yesterday. The fourth is shaping and applying risk management principles on both ingredient and manufacturing issues, and the fifth is representing members' interests on a variety of ingredient issues at both the state and federal levels.

Sohn: Dick, I know I am putting you on the spot here, but how would you rate Linda's staff efforts on these priorities so far?

Green: Well I believe that Linda is doing a great job. She is right on target. She developing an aggressive, but manageable, program of work for CHPA that is directly in line with the Association's mission, and focused on its priorities. Like I said, I think she is right on target.

Sohn: Since I already put you on the spot once Dick, I may as well go ahead and ask the one really hard-hitting question that CHPA's members want the answer to. How does the Association's financial picture look?

Green: Sure this is probably the most popular part of the annual meeting. And I believe that Roman Blazauskas (*vice president - finance and operations, treasurer, CHPA*) would be happy to answer that one.

Blazauskas: Thanks Mister Chairman. During 2002 the Consumer Healthcare Products Association maintained its status as the leader of the self-care industry while responsibly meeting its financial obligations.

The Association had revenues of \$9,239,000 and expenses of \$8,734,000, resulting in a contribution of \$505,000 to reserves. The Association's reserves as of December 31, 2002 were 44% of our net annual operating expenses. The recommended target is 40%. The 2003 budget contains programs and initiatives the Association plans to implement that will promote responsible and effective self-care. Mr. Chairman, the CHPA's financial picture for 2003 is positive as the Association continues to represent the self-care industry.

Sohn: Thanks for fielding that one Roman. Dick, I also know that new members of the Board are elected at this meeting. Could you please fill us in on who the new members of the Board are?

Green: Actually, I think the more appropriate person to handle that question is CHPA's Nominating Committee Chairman Charlie Hinkaty (*president, Del Pharmaceuticals, Inc.*). Charlie?

Hinkaty: Thank-you, Mister Chairman. Placed on your chairs this morning was a copy of the list individuals slated for seats on the board. Their names are also being shown on the overhead right now. I would like to congratulate Dick Green for his re-nomination and make special mention of the fact that Tim Hayes (senior vice president & region head, North America, Consumer Care Division, Bayer HealthCare LLC) has accepted the nomination to serve as the Chairman-elect of the Board.

Green: Thank you Charlie. Can I have a motion to elect all of these fine people to CHPA's Board of Directors? *Motion from Board member in audience.* Is there a second? *Second from Board member in audience.* All in favor? Yea. Opposed? Motion carries.

Sohn: Well congratulations to all of you. Linda, I hear that CHPA is extremely busy in the states this year. What's going on?

Suydam: Yes, it has been a surprisingly challenging year in the states. In fact, just this week we have had CHPA staff in Missouri, New Mexico, Iowa, and Tennessee. We have been tracking over 150 hot bills and are out there working with retailers to assure that consumers continue to have access to the safe and effective products they deserve. We know that illegal diversion of our products to methamphetamine is a real law enforcement problem and we are working with the DEA (Drug Enforcement Administration) on this. But denying consumers access to products is not the solution.

Sohn: Linda, I understand that FDA has been talking a great deal about bar-coding on unit-dose packages. What's that all about?

Suydam: Well in fact, just yesterday, FDA released a proposed rule on bar coding in the *Federal Register*. According to the proposal, it would require the addition of a bar code to medications intended to be dispensed in hospitals in single-unit packaging. This came about when HHS Secretary Tommy Thompson learned that drug errors in hospitals was a major reason for serious adverse events.

Sohn: (follow-up) Okay, but if it is in a hospital setting, could one of you please explain exactly are OTC medicines affected?

Green: Because OTCs are used in hospitals. CHPA has participated in FDA meetings on the subject and is preparing comments presenting the industry's perspective on the proposed rule. In our comments, CHPA points out that labeling, not coding, is the appropriate tool to address medication errors for OTC medicines in the consumer setting. We want to help provide suggestions to FDA on how to move forward in a practical and cost-efficient way.

Sohn: Dick, you just mentioned advocating FDA for a cost-effective approach. But bar coding is not the only regulatory issue that could have a financial impact. For example Linda, could you please talk a little bit about the Code of Federal Regulation Part 11 and what it means to CHPA's members?

Suydam: Absolutely: This is a very important regulation that effects electronic records and signatures and is part of FDA's GMP initiative. The proposal was tremendously burdensome but there has been progress to change the scope of the rule in ways that are consistent with industry's goals for a more reasonable and technically feasible approach to this issue. The MCC (Manufacturing Controls Committee) is engaged and making progress so stay tuned.

Sohn: Dick, Linda mentioned earlier that one priority area that CHPA is focusing on is Rx-to-OTC switch. Just to put things into perspective, exactly how many products have made the switch from prescription to nonprescription, or OTC status?

Green: Well, I think the numbers are just amazing. Would you believe that since 1976, over 70 ingredients, dosages, or indications have made the "switch" from prescription to OTC status? What that boils down to is that more than 700 medicine products available

over-the-counter today use ingredients and dosages that were available only by prescription less than 30 years ago.

Sohn: Linda, another one of the Association's priorities you discussed earlier is CHPA's efforts to enhance relations with FDA. But, could you please talk specifically about how CHPA has been working with FDA on OTC issues?

Suydam: This has been a multifaceted approach with usual channels – SAC (Scientific Affairs Committee) dialogue, FDA speakers at our MCC meeting and R&SDC (Research & Scientific Dialogue Conference), Commissioner McClellan and Sandy Kweder here, Janet Woodcock at the last Board meeting, and interactions at all levels with many of CHPA staff. One specific program I'd like to mention is jointly developed with FDA –educational sessions. We have received a very positive response from FDA on the first session which will be held in May on labeling, specifically creation and implementation.

Green: I would also like to point out that Linda's year is almost up and that she will soon be able to talk with key FDA staff on CHPA's behalf. That is going to be very helpful for us.

Sohn: Thanks Linda. And onto another subject. Dick, we talked about state issues earlier, but what is the Association telling folks on Capitol Hill?

Green: Well, first I would like to point out that CHPA is very pleased about the fact that for the first time in recent history, the President's proposed budget includes a specific monetary increase of \$1million dollars for OTCs. As far as what the Association is doing, we are extremely active in encouraging Congress to allow greater utilization of cost-effective healthcare options by allowing consumers to include over-the-counter medicines as a tax-deductible medical expense. We are also pushing for allowing consumers to use their flexible medical spending accounts to purchase nonprescription medicines.

Suydam: I'd like to add to what Dick was saying. Do you realize that 95 million Americans will have some sort of flex spending account in the next few years? Since we're hopeful that some switches are going to happen people should be able to use some of those set aside dollars for OTCs.

Sohn: I'd like to switch gears now to the international arena. Could both of you please share your thoughts on what is going on around the globe?

Green: Sure, a lot has been going on. For example, WSMI Director Dr. Jerry Reinstein retired and was succeeded by Dr. David Webber. And we are pleased that WSMI held their Board meeting in conjunction with this Annual meeting. We also just learned of some good news. Industry veteran Gary Balkema (*president, Consumer Care Division, Bayer Healthcare LLC*) has agreed to take over the WSMI Chairmanship sometime this spring.

Suydam: In addition CHPA has been working with WSMI to enhance global strategic alliances. As a result WSMI has statements from the World Medical Association and

the International Council of Nurses as well as the International Federation of Pharmacists supporting the important role of self-care as a part of the global healthcare system.

Sohn: Dick, I'd like to bring it back a lot closer to home now. Could you please tell me how the Association's audit report looks?

Green: Ah, second only in popularity to the Treasurer's Report. Once again, I am going to defer to an expert. Doug Rogers (*president, U.S. Healthcare Division, Wyeth Consumer Healthcare*), who serves on the Auditing Committee is here with us today. How do we look Doug?

Rogers: Thank you Mister Chairman. The Auditing Committee has received the independent auditor's report on the financial statements of the Consumer Healthcare Products Association for the year ended December 31, 2002. This report was prepared by the accounting firm of Johnson Lambert and Company. The financial statements and the accompanying notes were found to be in order by the Committee. These statements present fairly the financial position of the association and have received an unqualified opinion. Mr. Chairman, the Auditing Committee recommends the acceptance of the December 31, 2002 audit report.

Green: Thanks Doug. Could I please have a motion to approve the Audit Report? *Motion from Board member in the audience. A second? Second from Board member in the audience.* Those in favor? *Yea.* Opposed? *Motion carries.*

Sohn: Great, thank you. Linda, CHPA is always talking about the importance of outreach, but what is the Association actually doing about it?

Suydam: It's important to put outreach into the context of our overall communication strategy. Within that strategy we have three targeted goals; One, building the overall image of the OTC industry to enhance utilization. Two, the misuse and abuse of OTCs and three, the benefits of OTC products. With each of these we need to target our outreach partners in a focused way. We also need to heighten our consumer education efforts because better consumer education will also strengthen our industry.

Sohn: Linda, while we are on the subject of CHPA business, I understand that you have some new plans for your web site, is that true?

Sudyam: Yes, that's true. We've already made some significant additions in 2002 and more enhancements are planned. Our goal is to develop new features that help members conduct their day to day business. A good example that we're currently working on is a regulatory guidance e-library, where members can easily access important FDA and FTC policy papers and guidance. This will be up and running sometime this spring. In addition we want to provide consumers with better and more helpful information about OTC and Dietary Supplements.

Green: The CHPA staff is also looking for creative ways to bring more consumers to the site. Through a partnership with the National Women's Health Resource Center, we are developing a series of interactive quizzes on how consumers use dietary

supplements and OTC medicines. The goal is to learn as much about how consumers use our products as possible so that we may better tailor our consumer education projects in the future.

Sohn: Linda, Dick mentioned that one of your web site quizzes is going to focus on dietary supplements which reminds me of another issue. I understand that the long-awaited Good Manufacturing Practices for dietary supplements are just out. What will this mean to CHPA members?

Suydam: It will mean a new level of credibility for dietary supplement manufacturers. While the majority of CHPA members already employ extremely high manufacturing standards, this will add a new-line of defense against critics who wrongly say that the industry is unregulated.

Sohn: Unfortunately we are running out of time, do either of you have any concluding comments?

Suydam: Yes, I do. We've already mentioned that this AEC format is the result of a reinvention task force and the Business Program Committee, but I'd like to take this opportunity to thank all the CHPA staff, but especially Kass Kassouf, Maria Sarabia, and David Spangler for making sure that every detail was handled and it was an overall successful meeting.

Green: And I would like to ask this year's Business Program Committee Chairman Pat Lonergan (*president, partner, NUMARK Laboratories*) to join us up here so that I can present him with a token of our appreciation.

Lonergan joins the group on stage.

Sohn: I would like to thank you both Dick and Linda for joining me today. I think we all know a lot more about CHPA and its role as the voice of the industry.

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