

The mission of the CLMA is to increase awareness and utilization of custom manufactured contact lenses.

The Contact Report®

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THE CONTACT REPORT
Volume 2008, Issue 1

Niche Specialty Lens Market

It is my belief that the gas perm and custom soft lens contact lens manufacturers have recognized that we must embrace specialty lenses to be competitive in today's market. We know that gas perms, hybrid lenses and custom soft lenses score the highest success rate for health and vision in relationship to the compromised eye. Out of these contact lens categories, gas perms are the most frequently chosen for critical visual demands. Patients that collect into a potential niche specialty lens group are keratoconus, pellucid marginal degeneration, presbyopia, post trauma to the eye, post refractive surgery and corneal reshaping.

- **Keratoconus:** While keratoconus is not one of the most common eye diseases, it is by no means rare, estimated to occur in one out of every 2000 people in the general population. It is found in all parts of the United States and the rest of the world, with no significant geographic, gender, ethnic or social pattern.

- **Pellucid marginal degeneration:** PMD is rare and the exact incidence and prevalence are unknown. However, the incidence may be considerably underestimated, as this condition is often misdiagnosed as keratoconus. Like keratoconus, PMD is also found throughout the United States with no significant gender, ethnic or social pattern.

- **Presbyopia:** According to a US Census Bureau Report "An Aging World-2001," there were 100 million presbyopes in the US, 4 million people turning presbyopic every year and 10,000 people turning 50 every day. Staggering numbers from both eye health and marketing perspectives.

- **Post trauma:** It's no surprise that PubMed Central, a free digital archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health (NIH) reported that eyes that have undergone repair for corneal perforating injuries, with or without lens aspiration, were fitted with gas permeable contact lenses. The fitting pattern and the improvement in visual acuity by contact lens over spectacle correction were noted as very favorable for gas perm contact lenses.

- **Post refractive surgery:** Lasik vision correction has become one of the most popular elective surgical procedures performed in the United States. Over one million people have opted to undergo the procedure in the U.S. alone. Patients who opt to have lasik surgery most often have successful outcomes, however, 3% - 6% reported complications following their surgery.



Janice Schramm, President
Contact Lens Manufacturers Assn.

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Highlights:

- Specialty Lens Market
- Opportunity for CLMA members
- CLMA attendance at GKC 2008
- Gold level sponsorship of Educators at GKC
- Board of Directors meeting

Continuation of President's Message...

● **Corneal reshaping:** In the United States the prevalence of myopia has been estimated at 20%. Nearly 1 in 10 (9.2%) American children between the ages of 5 and 17 years have myopia. Approximately 25% of Americans between the ages of 12 and 54 years have the condition. A recent review found that 25.4% of Americans aged 40 years or over have at least 1.00 diopter of myopia and 4.5% have at least 5.00 diopters.

The potential for the special lens market is an opportunity for all of us. We are fortunate that we have numerous specialty lens resources to draw from. Many members of the CLMA (Contact Lens Manufacturers Association) attended the Global Keratoconus Conference in Las Vegas in January 2008. The participants, which included 400 registrants from 30 countries and another 100 sponsors and exhibitors, were all successful in accomplishing their goal of receiving expert insight, experience fitting sessions and had access to the most advanced products used in treatment. Additionally, the exhibitors had the opportunity to present their products and lens designs to a very serious minded group of gas perm and custom lens fitters. At the close of the 2008 GKC meeting, Carla Mack, OD, FAAO, announced that there are plans for another global conference in 2009. That conference may include topics to expand the range of specialty lens design presentations.



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(650)378-1424

CLMA Board of Directors and Sponsored Educators

As GOLD sponsors, the CLMA/GPLI was represented at a Fundamentals Presentation and a Breakfast Seminar, both presented by Dr. Ed Bennett. We also had a booth in the exhibit hall that drew attendees throughout the conference. Ed Bennett, OD, Executive Director of the GP Lens Institute, Janice Schramm, CLMA President, Pam Witham, Administrative Director of the CLMA and members of the CLMA board, Chris Pantle, Ken Leonhard, Bill Hoffman, David Bland and Lee Dickerson attended a luncheon for the educators of the schools of optometry. Ed and I officially welcomed the educators and reaffirmed our support of the schools. The winter CLMA Board of Directors meeting was also held at the GKC meeting on Sunday, prior to departure. We enjoyed a very productive conference and board meeting.

Tentative Date for CLMA Board of Directors meeting:

**Wednesday, June 25, 2008
AOA – Seattle, WA.**

Our next Board of Directors meeting will be held on Wednesday, June 25, 2008 (tentative) in Seattle, Washington at the American Optometric Association meeting.

CLMA/GP Lens Institute Exhibition Booth

CLSA—Inter-Continental Hotel, New Orleans, LA. March 5—8, 2008 **Booth #27**

Board of Directors representation: Ms. Janice Schramm, Mr. Lee Dickerson & Mr. Chris Pantle

AOA—Seattle, WA. June 26—28, 2008 **Booth #2308**

Board of Directors representation: Mr. Chris Pantle, Mr. Al Vaske

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CLMA Membership Services; Ken Leonhard & Chris Pantle, Co-Chairs

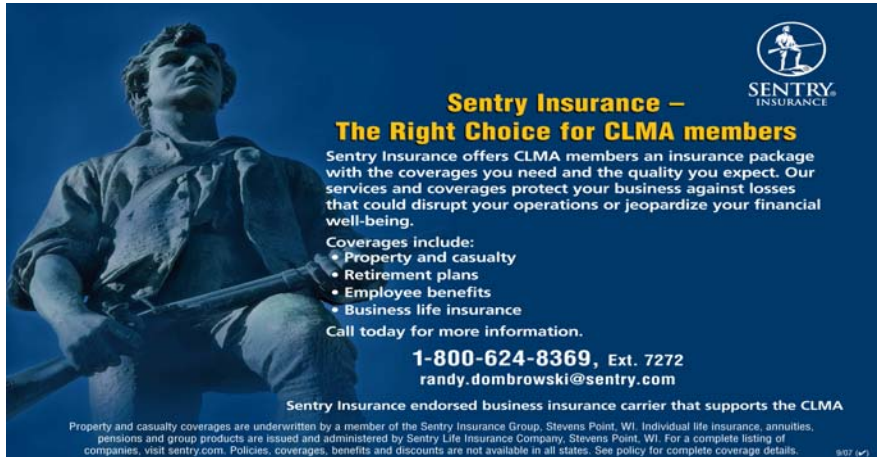
Ken@qualitycontactlens.com

Cpantle@dac-intl.com

Possibilities

- ▶ Sentry Insurance has been contacted for help with information on Association endorsed health insurance for CLMA member companies.
- ▶ Sam's Club or COSTCO Memberships
- ▶ Reduction of Credit Card Processing fees. Keeping more profit on every credit card sale/payment transaction by negotiating a group processing rate.

??What rewards program credit cards provide the best benefits to our member companies?? Let us hear from you.



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Call today for more information.
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randy.dombrowski@sentry.com

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Property and casualty coverages are underwritten by a member of the Sentry Insurance Group, Stevens Point, WI. Individual life insurance, annuities, pensions and group products are issued and administered by Sentry Life Insurance Company, Stevens Point, WI. For a complete listing of companies, visit sentry.com. Policies, coverages, benefits and discounts are not available in all states. See policy for complete coverage details.

Contact our CLMA endorsed business insurance agent Randy Dombrowski to obtain a quote for your business insurance.
A membership benefit from the CLMA

Membership Update

Please welcome **Mr. Wesley Raffles, Associated Contacts, Inc.** in Sarasota, FL as the newest CLMA Regular Member.

2036 Bispham Road
Sarasota, FL 34231
(941)921.1200

*CLMA 2008
Directory of
Membership —
coming soon to a
mailbox near you!*

One Special Member has decided not to renew membership for 2008. Pelican Products, Inc. (CLMA Associate member) has a new official representative with a new address. Contact CLMAAssociation@aol.com for this information.

CLMA Membership Directory— 2008

Work on the 2008 CLMA Membership Directory has started. The committee will soon be out there looking for advertisers and other industry related information to include in this year's guide. We would like to have a page that lists all the Optical Industry Trade Shows. Anyone with a listing could forward that to Pam (CLMAAssociation@aol.com).



Committee Co-Chairs: Chris Pantle and Ken Leonhard. Mr. Pantle is Vice-President of the CLMA representing DAC International. Mr. Leonhard represents Quality Contact Lens. Both are active members of the CLMA Board of Directors.

Internal Affairs Committee

Al Vaske, Chair

Vaske@lensdynamics.com

The Committee continues to monitor ALL expenditures for the CLMA to stay within the authorized budget.

CLMA Annual Golf Tournament

Make plans to attend the 47th Annual CLMA Meeting & Exhibition November 12—15, 2008 at the Renaissance Ross Bridge Golf Resort & Spa.

Hoover, Alabama

November 12 — exhibitor set up

November 13 8:00 AM Shotgun Start GOLF Tournament at

Robert Trent Jones Golf Trail

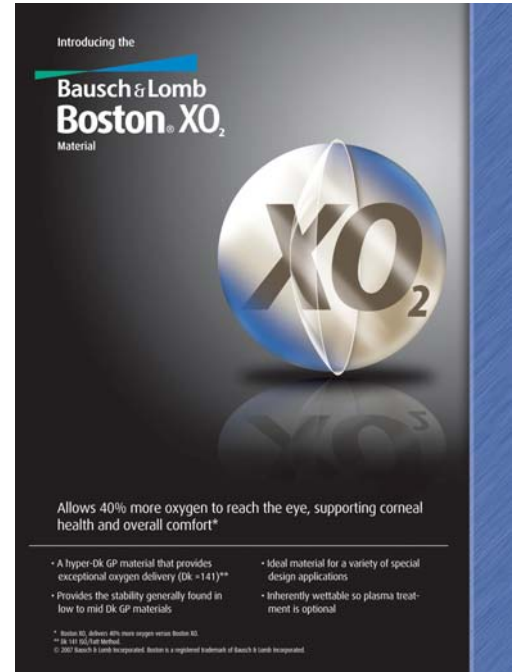
..David Bland, Convention Chair, david.bland@bausch.com

Seal of Excellence in Manufacturing for 2008

John Walfoort, Chair Technical Affairs Committee

Jwalfoort@walman.com

The Technical Affairs Committee would like to remind those that have been awarded the Seal of Excellence in Manufacturing Award for 2008 to use the logos for 2008.



Advertisement supplied by B & L The Boston Group, An Associate member supporting the CLMA membership.

“My idea of housework is to sweep the room with a glance.”

The American Legion Magazine/February 2008 p 64



FDA Registration Requirements

Daniel Bell, Government Affairs Committee Chair danbell12@aol.com

Daniel Manelli, ESQ; Legal Counsel for CLMA dmanelli@manellifisherlaw.com

Reconfirming previous information published in the newsletter of October 2007, the 2007 changes in FDA establishment registration and device listing procedures apply ONLY to companies who were actually required to register under the previous procedures and are still operating on the same basis. The new procedures require electronic filing and payment of an annual registration fee of \$1,706. They do not, however, create new registration or device listing obligations for companies who were not required to register or list under the previous procedures. If a company's manufacturing of contact lenses is performed solely as a so-called alternate manufacturing site (also termed a lens finishing laboratory by FDA), for a lens button manufacturer (*i.e.*, not having its own 510(k) or PMA), registration and listing was not required under the previous procedures and is NOT required now. Some companies operating only as alternate manufacturing sites may have submitted registration and listing forms in the past under the impression that they were required to do so. Such prior submissions need not be renewed.



Further clarification on who must register with the FDA establishment and device listing procedures.

GP Product Directory Listing

Check out your company's GP product listing on www.gpli.info under the searchable database listing.

Make sure everything is accurate and up to date.

A CLMA membership benefit.



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ABO NCLE National Education Conference

Training to Improve an Opticians Product Expertise and Business Skills

2008 ABO-NCLE
NATIONAL EDUCATION
CONFERENCE

September 19-21, 2008
Cincinnati, Ohio

The first ever ABO NCLE National Education Conference will take place September 19—21, 2008 in Cincinnati, OH. The conference will offer three days of training and education to improve an optician's technical, professional, managerial and personal performance. Over 100 hours of ABO and NCLE approved education has been developed with education partners; NAO, OAA & CLSA. This meeting will offer more ABO-NCLE CE credits, including hands-on training, than any other convention in history.

Since product expertise is vital to opticians serving patients, the *Optical Showcase* Exhibit Hall will also be an education center.

Exhibit Hall "Show and Tell"
Exhibit Hall "Visit and Learn"

The conference will be held at the Duke Energy Center, a state-of-the-art convention facility. The Millennium is the host hotel conveniently attached to the convention center with very affordable room rates with early reservations.

To find out additional details and register at

www.abo-ncle-conference.com.

**Exhibit your
contact lens
products, lens
designs at the
ABO NCLE
National
Education
Conference.**

**Expected
attendance is
1,000 eye care
professionals**

Keynote Speaker Announced!

Jan Svochak, Program Committee Chair jan_svochak@tfoptics.com

Dr. Joe Benjamin has accepted our invitation to be the keynote speaker at the 2008 CLMA Annual Meeting and Exhibition. With his academic career at the UAB—Birmingham College of Optometry and his enthusiastic approach to contact lenses, his address to the meeting attendees will be an positive beginning to our meeting.

Dr. Benjamin was instrumental in the study of Dk standard testing measures for the CLMA as well as the 2006 Dr. Joseph Dallos Award winner.



Dr. William "Joe" Benjamin

Fitter Locator Coming Soon

GP Lens Committee, Dr. Rob Breece, Chair drbreece@yahoo.net

Work is progressing on the new GP contact lens Fitter Locator software that will interface from www.gpli.info (eyecare professionals) as well as www.contactlenses.org (consumers). This global latitude searchable database will allow the keying in of a zip code and the list will provide the nearest eye care professional (multiple listings if available) to that location.

The four categories to be included are:

- General GP Lens Fitter
- Irregular Corneas (including keratoconus, post-surgical and irregular astigmatism)
- Bifocal/Multifocal GP contact lenses
- Corneal Reshaping/Orthokeratology

The GP Lens Institute's Advisory Group are the first eyecare professionals that will be loaded into the software. Next phase will be CLMA member company recommendations.

Quality Systems Regulation Educational Forum on Design Controls is scheduled for April 4, 2008 in Dallas Texas.

Naomi J. Svochak, Public & Professional Information Committee

jo_svochak@tfoptics.com

To ensure that good quality assurance practices are used for the design of medical devices and that they are consistent with quality system requirements worldwide, the Food and Drug Administration revised the Current Good Manufacturing Practice (CGMP) requirements in 1996 by incorporating them into the Quality System Regulation, 21 CFR Part 820. An important component of the revision is the addition of design controls.

The objectives of this educational forum are to assist manufacturers in understanding the intent and implementation of the regulation.

The following topics will be discussed:
Design Control Overview and Planning
Design Inputs and Outputs
Design Validation and Verification
Design Transfer
Design Change and Supplier Controls
Design History Files

The Forum will be held on April 4, 2008, from 8 am to 5 pm at the Adam's Mark Hotel Dallas, 400 North Olive Street, Dallas, TX. For more information, please visit www.fmdic.org or email david.arvelo@fda.hhs.gov.

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Lincoln, Nebraska 68529

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Fax: 402-465-4187
Email: CLMAssociation@aol.com

CLMA
Contact Lens Manufacturers Association



**www.CLMA.
net**

**47th Annual CLMA Meeting & Exhibition
Renaissance Ross Bridge Golf Resort & Spa**

Hoover, Alabama

November 12— 15, 2008

Exhibitor move in—

Wednesday, November 12

Fully equipped exhibit hall arena

lathes, equipment, solutions, materials,

support services for

manufacturing contact lenses.

**Contact Jim Drain, Associate Members Com-
mittee Chair for more information.
Jdrain@dac-intl.com**

Contact Lenses Today

Industry related press releases (excluding financial releases or info on company sponsored clinical studies) can now be sent to:

Kathy Shafer at ShaferK@lwwvisioncare.com

for possible inclusion in the weekly email *Contact Lenses Today*, edited by Dr. Carla Mack.

They are happy to print viable news about new products!

Next issue of THE CONTACT REPORT.....April, 2008