GOVERNMENT & REGULATORY AFFAIRS UPDATE

VISION EXPO EAST 2015

March 19, 2015
TVC Government Relations

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Washington, DC
Who is Bryan Cave?

• Bryan Cave LLP is one of the 25 largest law firms in the world with global reach and a long history of success in federal and state government relations and regulatory affairs

• BC Government Relations is comprised of a bipartisan and bicameral cadre of former Members of Congress, White House staff, Senior Capitol Hill Aides, Federal Agency decision-makers as well as State and local elected officials

• TVC & BC have been successful government relations partners for most of the last decade on Capitol Hill and within the Administration
Supporting Your Policy Agenda

Key Relationships:
- Administration – Agencies (HHS, Customs and Border Patrol, U.S. Trade Representative, CMS, FDA, etc.)
- Members of Congress (Business, Trade, Health Care, etc.)
- Congressional Caucuses (Vision Caucus, Medical Device Caucus, etc.)
- Political Support – Making Friends Before We Need Friends

Support:
- Policy Intelligence & Insight – Early identification of key policy development
- Representing TVC at Congressional, Fed Agency, and Stakeholder policy development meetings, hearings, mark-ups and other targeted forums
- Developing strategies to anticipate, respond and impact policy proposals
Overview of Targeted Vision Council GR Activities
TVC & Federal Agency Decision-Makers

- Assistant Commissioner, U.S. Customs and Border Protection (CBP) and Senior Staff including Port Security Field Office Directors, Interagency Branch, Compliance, etc.
- HHS Office of the Secretary ACA Outreach Staff regarding Children’s Vision Benefit
- Deputy U.S. Trade Representative and senior staff from the Office of the USTR regarding key trade issues with China as well as the TVC delegation visit

GOAL: Educating, cultivating and establishing dialogue with senior political leadership within federal agencies
TVC Congressional Briefings Grow in Attendance on Hill

• TVC Leadership educated audiences of more than 40 targeted Congressional offices on low vision, UV protection, etc.
• House & Senate senior policy aides from key committees of jurisdiction as well as the Congressional Vision Caucus in attendance.
• UV eyewear provided to Capitol Hill staff.
• Education for Congressional staff regarding UV protection and vision health.
TVC Establishing Local Relationships to Influence National Policy

• Successful Congressional tours with Members of Congress visiting TVC member company facilities
• Increased support of Members of Congress important to the industry with jurisdiction over issues
• Connecting the dots between local state issues and concerns with federal policy development to improve oversight & reg environment for TVC member companies
• Meeting with Governors, Agencies, & Congress
Medical Device Tax

• Eyeglasses, contact lenses and hearing aides
• TVC lobbying of key health care committees and congressional leadership for “carve out”
• Association lobbied both independently as well as with coalition partners
• Ripe for Repeal
Tax Free Health Spending

• TVC was early leader in Coalition to support repeal of the ACA provisions lowering FSA’s from $5K to $2,500
• Partners include ADA, AHIP, Chamber of Commerce
• TVC supported FSA Congressional Champions Congressman Paulsen (R-MN) and Senator Hutchison (R-TX) – Repeal Legislation
• Vision & Dental have become key examples for repeal
• New generation of bills introduced this Congress increasing FSA & HSA
Current Focus Areas
Ongoing Efforts With Policy Reform

• FSA/HSA Expansion
• Pediatric Vision Benefit / ACA Next Steps
• Tax Reform
• Patent Reform
• Regulatory Support
Business, Commerce and Trade Agenda

- Beyond direct health care focus (HHS, FDA, CMS, etc), TVC is continuing to target and cultivate key relationships with business and trade Agency federal decision-makers
- Meetings and continued sit downs with Customs and Border Patrol, Port Security, etc.
- Deputy U.S. Trade Representative, Office of USTR
Upcoming Activities

- Build on Success of TVC Congressional Briefings on Capitol Hill
- Increased presence by TVC member companies on Capitol Hill and within targeted Agencies
- District Congressional tours of TVC member company facilities – 4 Very Successful Visits by Members of Congress
- Enhanced grassroots activities
- Political Action Committee
**Issue Update**

> **UNIQUE DEVICE IDENTIFIER**

> Most TVC products are Class I medical devices.

> UPC code are UDI; must report into GUDID.

> September 25, 2018 for Class I devices.

> Existing inventory gets three year exemption.

> TVC looking into use of OPC as UDI.

> TVC working with Rx lens manufacturers on potential exemption.
Issue Update

> FDA, Customs, ISO and ANSI Round Up

  > Status quo on inspection of shipments.
  > Trade Legislation still in limbo.
    > GSP renewal.
    > Miscellaneous Tariff Bill.
    > Trans-Pacific Partnership.
    > Trans-Atlantic Trade and Investment Partnership.
    > Trade Promotion Authority.
Issue Update

> FDA, Customs, ISO and ANSI Round Up

> ISO Sunglass Standards 12311 and 12312-1.
  > Replaces EN 1836.
  > Now in use.

> Movement to replace ANSI frame standard with ISO standard.

> ANSI reading glass standard to be reviewed for:
  > Sunreaders.
  > Bifocal readers.
Issue Update

> CALIFORNIA PROP 65

> Enforcement against optical products decreases.

> BpA litigation

> Injunction was lifted.

> ACC requested new trial; hearing on April 3rd.

> BpA being considered for possible listing.
Issue Update

> CALIFORNIA PROP 65 – Possible Changes:

> Issued proposed changes.

  > Two years after date of promulgation.

> Change warning language.

  > Include the following symbol.
Proposed Revision for Consumer Products—

> “WARNING: This product can expose you to a chemical known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to www.P65 Warnings.ca.gov”.

Proposed Revision for Consumer Products Containing Phthalates—

> “WARNING: This product can expose you to a chemical such as phthalates known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to www.P65 Warnings.ca.gov”.
Clarifies Ways to Comply.

> Affixing a warning label to the product or its immediate container or wrapper, or
By providing written notice to the retailer that:

- States to the retailer that a warning is necessary;
- Includes the exact name or description of the product or the specific identifying information for the product, such as an UPC;
- By either:
  - Providing all necessary warning material such as labels, point of sale signs, tags, etc., to the retailer, or
  - Offering to provide such materials at no charge to the retailer;
- Get written acknowledge from retailer it received this written notice; and,
- Gets the retailer at least once every 180 days during the period the product is sold in California to renew and acknowledge in writing that it received the written notice.
Issue Update

> This shift compliance to the retailer.

> Should ease inventory issues.

> Lastly, parties can allocate legal responsibilities among themselves and it will bind the parties.
Questions

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Topics

- NLRB Update
- Noncompetition Agreements
NLRB Basics

- National Labor Relations Board ("NLRB") has authority to (1) manage union elections and (2) review and remedy unfair labor practices
- NLRA protects "concerted activity" between workers (union or otherwise)
- 5-person Board: all appointed by the President with consent by the Senate
Recent NLRB Cases and Rules

- Employee use of company email (*Purple Communications*)
- Profane language and offensive behavior (*Inova Health System*)
- Dress code policies (*Walmart*)
- “Ambush election” rule
Noncompetition Agreement Law Update

- Basics: to be enforceable, noncompete agreements must be: (1) reasonable (geographic scope and duration); and (2) necessary to protect the employer.
- Vary from state to state: e.g., virtually prohibited in California; enforced in Texas and Massachusetts.
Several recent decisions have focused on the issue of “separate consideration” for post-hiring agreements.

States vary on whether continued employment is sufficient to make noncompete agreements enforceable.

What is separate consideration?: bonus, promotion, special training, employment for certain period.
Intellectual Property Rights

© Owner gets exclusive right to copy, distribute, display, perform and create derivative works; *does not protect underlying ideas*

Trade Secrets Protects material which is not generally known - value is in keeping the information secret; *protects underlying ideas*

Owner gets exclusive right to prevent others from making, using, or selling the patented technology; *protects underlying ideas*

® TM Signifies ownership and quality of goods and services sold under the mark; *protects owner’s rights to mark; based on use*
What is a License?

- General license
- Intellectual Property ("IP") license
**Parties**

- “Licensor”: Owner of the technology or IP
- “Licensee”: Party who receives the right to use the technology or IP
Why License IP?

- Sale v. License

- What does an IP license do?

- Owner can “mix and match” legal rights to meet both owner and customer business needs
Types of Licenses

- Exclusive
- Non-exclusive
Types of Licenses

- Joint license
- Cross license
Strategic Considerations

- Revenue
- Maintain Confidentiality of IP
- Scope of license
Key Elements of a License

- Grant of license
- Payment
- Ownership of IP
Key Elements of a License

- Intellectual Property obligations
- Indemnification
Key Elements of a License

- Limitation on liability

- Confidentiality
What Are Typical Licensing Issues?

- Ambiguity
- Ownership of IP
- IP infringement and indemnification
- Improper license term
- Failure to clearly articulate pre-existing IP
Licensee Tips

- Clearly define “Licensee”
- Seek broader license scope
- Know your obligations, understand key elements, and make sure they are all clearly defined
- Avoid re-use of previous license agreements and/or standard form documents
- Consider cross licensing
- Address all possible aspects of IP Ownership
Thank you!

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**Key Industry Trends**

Aging populations driving demand for enhanced and expanded vision health

- 10.84% growth between 2013 and 2020

65 and older population will go from 40.3M in 2010 to 54.8M in 2020 and 72.1M in 2030

- 12% of 65 plus year old people will need eye care services
- 15 M Medicare beneficiaries have elected a Medicare Advantage plan

Shortage of providers creating pressure on delivery models

- ASCRS formed a task force in 2013, Integrated Ophthalmic Managed Eye Care Delivery (IOMED)
- Local Area Delivery System (LADS) concept
Managed Care Environment

Medicare reimbursements the same for OD/MD’s for medical care
  • Hub and spoke concept very efficient
  • Similar to physician extenders with OD’s being involved with large MD practices
  • Optometric care positioned for ACO’s

Medicaid lives projected to reach 75M+ by 2020.
  • Vision and Dental are key benefits for Medicaid
  • Heavy pressure from low cost of covered materials

Eye Care services easy to “carve” out for the health plan system due to essentially no hospital involvement.
  • Designated lab services could be reimbursement driven