Regulatory Update: Public Affairs, NCPA, IACP

Robert “Bud” Cramer
Doug Hoey, RPh, MBA, NCPA CEO
John Voliva, RPh
International Seminar
Houston, TX
November 10-12, 2016
Disclosure

Amy Shank is employed by PCCA. Bud Cramer is employed by FTI Consulting. Doug Hoey, RPh, MBA, is CEO of NCPA. John Voliva, RPh, is Executive Vice President at IACP.

Professional Education Services Group staff have no financial interest or relationships to disclose.
Disclosure

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Educational Grant Support

This continuing education activity is supported by an educational grant from PCCA.
Learning Objectives

• At the conclusion of this activity, the participant will be able to:
  – Discuss the impact of proposed legislation on compounding pharmacies and how it can affect the profession.
  – Review Retroactive Payment Clawback Legislation
  – Describe federal and state legislative actions underway to regulate compounding.
ELECTION ANALYSIS

2016
CONGRESSIONAL ELECTION
Balance of Power in Congress

NUMBER OF SENATE SEATS CURRENTLY HELD BY EACH PARTY

46 Democrats

54 Republicans

* Independents (Gray) Caucus with Democrats

NUMBER OF HOUSE SEATS CURRENTLY HELD BY EACH PARTY

186 Democrats

246 Republicans

3 Vacancies

NOTE: All House Members up for reelection

34 Senate seats were up for grabs this cycle. 24 of those seats were held by Republicans, giving Democrats a chance to tilt the scale of power. Democrats needed to net four seats to win control of the Senate if Hillary Clinton were to win the presidency, and five seats if Donald Trump were to win.

Republicans held their largest House majority since the 1928 Election. Republicans had the advantage in the House, as the Democrats would have needed to win an additional 30 seats to take the House.
Who’s In Congress?

Approximately half of all House Members come from business backgrounds, not political or public service backgrounds. About 40% of the Senate comes from a business background. Meanwhile, fewer than half of all Members in the 114th Congress have legal training. Currently, Congress is comprised of the lowest percentage of lawyers in history.
Who’s In Congress?

MEDICAL PROFESSIONALS

**Senate**
3 Physicians, 1 Optometrist

**House**
15 Physicians, 3 Dentists, 3 Veterinarians, 5 Nurses,
3 Psychologists, 1 Pharmacist
## Gavels up for Grabs

### Preview of Key Committee Leadership Positions -- 115th Congress

If Republicans Retain a Majority in the Senate...

<table>
<thead>
<tr>
<th>Committee</th>
<th>Chairman</th>
<th>Ranking Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finance</td>
<td>Orrin Hatch (UT)</td>
<td>Ron Wyden (OR) ♦</td>
</tr>
<tr>
<td>Banking, Housing, and Urban Affairs</td>
<td>Richard Shelby (AL)</td>
<td>Sherrod Brown (OH)</td>
</tr>
<tr>
<td>Health, Education, Labor and Pensions</td>
<td>Lamar Alexander (TN)</td>
<td>Patty Murray (WA) ♦</td>
</tr>
<tr>
<td>➢ Health Subcommittee</td>
<td>Mike Enzi (WY)</td>
<td>Bernie Sanders (VT)</td>
</tr>
<tr>
<td>Appropriations</td>
<td>Thad Cochran (MS)</td>
<td>Patrick Leahy (VT) ♦</td>
</tr>
<tr>
<td>➢ Agriculture Subcommittee</td>
<td>Jerry Moran (KS) ♦</td>
<td>Jeff Merkley (OR)</td>
</tr>
<tr>
<td>Armed Services</td>
<td>John McCain (AZ) *</td>
<td>Jack Reed (RI)</td>
</tr>
</tbody>
</table>

If Republicans Retain a Majority in the House...

<table>
<thead>
<tr>
<th>Committee</th>
<th>Chairman</th>
<th>Ranking Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ways and Means</td>
<td>Kevin Brady (TX)</td>
<td>Sander Levin (MI)</td>
</tr>
<tr>
<td>Energy and Commerce</td>
<td>Joe Barton (TX) **, John Shimkus (IL), Greg Walden (OR) [Fred Upton (MI) term limited]</td>
<td>Frank Pallone (NJ)</td>
</tr>
<tr>
<td>➢ Health Subcommittee</td>
<td>Brett Guthrie (KY), [Joe Pitts (PA), retiring]</td>
<td>Gene Green (TX)</td>
</tr>
<tr>
<td>Financial Services</td>
<td>Jeb Hensarling (TX)</td>
<td>Maxine Waters (CA)</td>
</tr>
<tr>
<td>Appropriations</td>
<td>Rodney Frelinghuysen (NJ) ** [Hal Rogers (KY) term limited]</td>
<td>Nita Lowey (NY)</td>
</tr>
<tr>
<td>➢ Agriculture Subcmte.</td>
<td>Robert Aderholt (AL)</td>
<td>[Sam Farr (CA), retiring]</td>
</tr>
<tr>
<td>Armed Services</td>
<td>Mac Thornberry (TX)</td>
<td>Adam Smith (WA)</td>
</tr>
</tbody>
</table>

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## Key Senate Races

### Polling

<table>
<thead>
<tr>
<th>State</th>
<th>Republican</th>
<th>Democrat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NV</td>
<td>JOE HECK</td>
<td>CORTEZ MASTRO</td>
</tr>
<tr>
<td>WI</td>
<td>RON JOHNSON</td>
<td>RUSS FEINGOLD</td>
</tr>
<tr>
<td>IL</td>
<td>MARK KIRK</td>
<td>TAMMY DUCKWORTH</td>
</tr>
<tr>
<td>IN</td>
<td>TODD YOUNG</td>
<td>EVAN BAYH</td>
</tr>
<tr>
<td>OH</td>
<td>ROB PORTMAN</td>
<td>TED STRICKLAND</td>
</tr>
<tr>
<td>PA</td>
<td>PAT TOOMEY</td>
<td>KATIE MCGINTY</td>
</tr>
<tr>
<td>NC</td>
<td>RICHARD BURR</td>
<td>DEBORAH ROSS</td>
</tr>
<tr>
<td>NH</td>
<td>KELLY AYOTTE</td>
<td>MAGGIE HASSAN</td>
</tr>
<tr>
<td>FL</td>
<td>MARCO RUBIO</td>
<td>PATRICK MURPHY</td>
</tr>
</tbody>
</table>

*Source: Cook Political 9/14/16*
The Future of Capitol Hill
THANK YOU!

Hon. Bud Cramer
FTI Consulting
(202) 657-2900
Community Pharmacy and Uncle Sam: It’s Complicated

B. Douglas Hoey, RPh, MBA, NCPA CEO
NCPA - Protecting Your Right to Compound

• NCPA Compounding Committee guides our positions (focused on 503A)
• Active participant in FDA Listening Sessions, PCAC Bulk Drug Substance Nominations, DQSA stakeholder coalition
• Top issues of concern
  – Office use compounding
  – MOU
  – Inspections
  – USP Monograph issue
  – Essential copies
  – Creation of bulk positive list
  – PCAC processes and makeup
NCPA - Protecting Your Right to Compound

• NCPA voicing concerns with PCAC processes and makeup
  – Inadequate PCAC member selection and renewal processes
  – FDA’s insistence that any bulk drug substance not voted onto the positive list can easily be obtained via the investigational new drug (IND) process
  – Unequal time allotted for nominators to defend substances and respond to committee questions
NCPA - Protecting Your Right to Compound (cont’d)

• NCPA voicing concerns with PCAC processes and makeup
  – FDA’s indication that it does not consider USP monographs for dietary supplements to be “applicable” USP or NF monographs, when no basis exists for FDA to exclude these monographs
  – A confusing nominating and review process that leaves many unanswered questions for health care practitioners and patients who rely on compounds
NCPA - Protecting Your Right to Compound

• Compounding “Best Practice” Principles Forum
• Live meeting and series of calls
  – NASPA, NCPA, IACP, APhA, PersonalMed, ACHC/PCAB, NABP, ACA
• Development of draft *Guidelines for Quality Compounded Preparations*
• Payer “buy-in”
• Dissemination of *Guidelines* to relevant stakeholders
Changing Landscape for Community Pharmacy

• Costly DIR “claw-backs”

• Despite being on the front lines of health care delivery, inability to be reimbursed under Medicare Part B for services outlined in their state’s existing scope of practice (Pharmacy Provider Status).

• Pharmacy services network being formed locally in a number of states
  — Payment for value versus frequency of services

• Payment for performance? Less punishment for performance?

• Not all pharmacies are the same!

• PBMs having to do a lot of explaining!
The Retroactive Payment Clawback Legislation

• **What would it do?**
  – Require the PBM to keep its payment adjudication “promise”
  – Would provide payment predictability
  – Would provide some level of transparency in PBM contracting; actual pharmacy payment vs. effective pharmacy payment would be known up front

• **What are its chances?**
  – Opportunities in this Congress
  – Momentum for 2017

• **Is this the ultimate panacea for DIRs?**
  – The legislation is one first step forward
The Retroactive Payment Clawback Legislation

• Tell me what to do
  – Contact your US Rep and Senators and tell them their support for this amendment *this year* is critical
  – Give them the bill numbers
    • Senate = S.3309
    • House = H.R. 5951
  – NCPA makes it easy on-line under Grassroots tab

How have pharmacies reacted?
  – 7,500 messages through NCPA’s system to Congress in less than 3 weeks (point of reference: there were 8,000 messages from pharmacies about ESI-Medco in 8 months)
# Trying to Follow the EpiPen $$$ Trail

<table>
<thead>
<tr>
<th>Entity</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mylan</td>
<td>$274</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>$20 (estimate)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>$25-35</td>
</tr>
<tr>
<td>Health Plan</td>
<td>$$$$$</td>
</tr>
<tr>
<td>Broker</td>
<td>$$$$$</td>
</tr>
<tr>
<td>PBM</td>
<td>$$$$$</td>
</tr>
<tr>
<td>Consumer/Employer pays</td>
<td>$608</td>
</tr>
</tbody>
</table>
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www.ncpanet.org
(800) 544-7447
IACP Update:
What’s Happening on the Hill / FDA / DQSA Coalition

John Voliva, RPh
Executive Vice President
International Academy of Compounding Pharmacists
Congress

• Busy year
• Appropriations language tackling office use, MOU & inspections
  – Letters from Congress to FDA
  – Rep. Morgan Griffith - MOU
  – Sen. Rand Paul - office use
• Questions during hearings and floor speeches
• Rep. Buddy Carter - office use
FDA

- PCAC - 3 meetings
- Stakeholder listening session
- Notice on inspections
- Inter-governmental meeting with the states [MOU]
FDA (cont’d)

• Guidances
  – Interim policy on compounding using bulk drug substances (FINAL)
  – Hospital & health system compounding
  – Prescription requirement under Section 503A
  – Compounded drug products that are essentially copies of a commercially available drug product
  – Insanitary conditions at compounding facilities
States

• IACP is beginning to work more closely with Boards of Pharmacy and State Pharmacy Associations
• NASPA relationship
• Major issue on the table: USP <800>
• Keeping tabs on actions by the boards and state capitolts via IACP Compounders Stateside
• Will be looking to become more active in comments and testimony, working with the State Pharmacy Associations.
DQSA Coalition

- 30+ members representing pharmacist, physician / practitioner, and patient advocacy groups
- Requesting for oversight hearing on DQSA
- A legislative correction to Section 503A on the horizon?
- The Coalition is our industry’s biggest tool in our toolbox
- Monthly meetings, active participation, great collaboration
- End goal: ensure groups work together on compounding issues, not against
What’s in store for 2017?

- Continue strengthening and exploring new relationships on The Hill
- Greater member involvement in many aspects of IACP
- Look to bring more clarity to the current regulatory atmosphere
- Build on the great work of the Coalition
- Strengthen IACP’s committees and structure
- Work to build a Coalition of State Pharmacy Associations
- FIX DQSA!
Thank you
Obtaining CE

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