

Compounding Pharmacy Legislation and the Potential Dramatic Impact on Home Infusion

May 8, 2013

1:00 – 2:30PM Eastern Time

Talk Infusion

The NHIA Membership Forum





Moderator

- Russ Bodoff, NHIA President and CEO



Presenters

- Kendall Van Pool, NHIA VP of Legislative Affairs
- Alan Parver, Esq., Polsinelli Shughart, NHIA Legal Counsel



Call Overview

- Update on Capitol Hill Activity to Review Possible Breakdowns in Oversight Related to Meningitis Outbreak
- Update on Capitol Hill Timeline for Legislative Efforts
- Review of Draft Legislation Disseminated by the Senate Health, Education, Labor and Pensions (HELP) Committee
- Review of NHIA Response to the HELP Committee Draft Legislation
- **Call for NHIA Member Action**



Ken Van Pool

Vice President of Legislative Affairs



Capitol Hill Oversight Overview

- Two Committees Have Jurisdiction Over Food and Drug Administration (FDA) Legislation
 - Senate HELP Committee
 - House Energy and Commerce Committee



Capitol Hill Oversight Overview

- House Energy and Commerce Committee
 - Currently Focusing on Investigating FDA
 - No Committee Proposed Legislative Text (Yet)
 - Possible Action on Compounding Legislation as Part of Track and Trace Legislation
 - Democrat amendments will likely be similar to Senate HELP Committee Draft Legislation
 - It is unclear if Republicans will be accepting compounding provisions in the Track and Trace legislation or if they will try to keep it “clean”



House Energy and Commerce Committee - Republicans

Fred Upton (MI)- Chair
Ralph Hall (TX)
Joe Barton (TX)
Ed Whitfield (KY)
John Shimkus (IL)
Joseph R. Pitts (PA) – Health Subcommittee Chair
Greg Walden (OR)
Lee Terry (NE)
Mike Rogers (MI)
Tim Murphy (PA)
Michael C. Burgess (TX)
Marsha Blackburn (TN) - Vice Chair
Phil Gingrey (GA)
Steve Scalise (LA)
Bob Latta (OH)

Cathy McMorris Rodgers (WA)
Gregg Harper (MS)
Brett Guthrie (KY)
Pete Olson (TX)
David McKinley (WV)
Leonard Lance (NJ)
Bill Cassidy (LA)
Cory Gardner (CO)
Mike Pompeo (KS)
Adam Kinzinger (IL)
Morgan Griffith (VA)
Gus Bilirakis (FL)
Bill Johnson (OH)
Billy Long (MO)
Renee Ellmers (NC)

Kendall Van Pool



House Energy and Commerce Committee - Democrats

Henry Waxman (CA) - Ranking Member
John D. Dingell (MI)
Edward J. Markey (MA)
Frank Pallone Jr. (NJ)
Bobby L. Rush (IL)
Anna G. Eshoo (CA)
Eliot L. Engel (NY)
Gene Green (TX)
Diana DeGette (CO)
Lois Capps (CA)
Michael F. Doyle (PA)
Jan Schakowsky (IL)

Jim Matheson (UT)
G. K. Butterfield (NC)
John Barrow (GA)
Doris O. Matsui (CA)
Donna Christensen (VI)
Kathy Castor (FL)
John Sarbanes (MD)
Jerry McNerney (CA)
Bruce Braley (IA)
Peter Welch (VT)
Ben Ray Lujan (NM)
Paul Tonko (NY)



Capitol Hill Oversight Overview

- Senate HELP Committee
 - Released Draft Legislative Text for Comment on April 26, 2013
 - NHIA Commented on May 3, 2013
 - Legislative Hearing Tomorrow (5/9/2013)
 - “Mark Up” in Committee by End of the Month
 - “Mark Up” most likely will be in conjunction with Track and Trace legislation
 - Senate Floor Action This Summer (Unclear on Exact Month)



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Senate Health, Education, Labor, and Pensions (HELP) Committee

Democrats

Chairman: Tom Harkin, Iowa
Barbara A. Mikulski, Md.
Patty Murray, Wash.
Bernard Sanders, Vt.
Bob Casey, Pa.
Kay Hagan, N.C.
Al Franken, Minn.
Michael Bennet, Colo.
Sheldon Whitehouse, R.I.
Tammy Baldwin, Wis.
Christopher S. Murphy, Conn.
Elizabeth Warren, Mass.

Republicans

Ranking member: Lamar Alexander, Tenn.
Michael B. Enzi, Wyo.
Richard M. Burr, N.C.
Johnny Isakson, Ga.
Rand Paul, Ky.
Orrin G. Hatch, Utah
Pat Roberts, Kan.
Lisa Murkowski, Alaska
Mark Steven Kirk, Ill.
Tim Scott, S.C.

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Alan Parver NHIA Policy Counsel



Senate HELP Draft Legislation

- Defines “compounding”
- Creates two types of compounding pharmacies that will be regulated differently
 - Compounding Manufacturers
 - Traditional Compounders
- Gives the Secretary of Health And Human Services (HHS) the authority to outlaw compounding of certain drugs and the use of certain bulk substances used to compound



Senate HELP Draft Legislation

- Compounding Manufacturers
 - An entity that compounds a sterile drug prior to or without receiving a prescription and introduces such drug into interstate commerce
 - OR**
 - Any entity that **pools sterile products**, or that repackages sterile, single-use, preservative-free vials



Senate HELP Draft Legislation

- Compounding Manufacturers Oversight
 - All practices of a Compounding Manufacturer are regulated by the FDA (even activities that are not within the definition that leads to the designation of being a Compounding Manufacturer)
 - Compounding Manufacturers must meet many of the Good Manufacturing Practices requirements that are imposed on drug manufacturers
 - Compounding Manufacturers **cannot be licensed as pharmacies**
 - Other provisions include: registration, fees, inspection, and adverse event reporting



Senate HELP Draft Legislation

- Traditional Compounders
 - A licensed pharmacist in a state-licensed pharmacy or a licensed physician or licensed veterinarian that compounds -
 - Upon receipt of a prescription order for an identified individual patient
 - Does not meet the definition of Compounding Manufacturer



Senate HELP Draft Legislation

- Traditional Compounders Oversight
 - An allowance is made for some limited advance compounding based on a “history” with a licensed pharmacist, licensed physician or licensed veterinarian (no mention of other types of practitioners, i.e. discharge planners)
 - No mention of limited batch compounding (may need clarification)



Senate HELP Draft Legislation

- Provisions that regulate the practice of both Compounding Manufacturers and Traditional Compounders
 - Do not compound list
 - Restrictions on use of certain bulk ingredients



Senate HELP Draft Legislation NHIA Concerns

- Any entity that pools sterile drugs is considered a compounding manufacturer
- Loss of pharmacy license for compounding manufacturers
- All sterile compounding can lead to being a compounding manufacturer (not just high-risk by USP <797> definition)
- Limited allowance for advanced compounding and batch compounding
- Overly broad Secretarial authority to regulate drugs that are compounded and the bulk product that is used in compounding



Ken Van Pool

Vice President of Legislative Affairs



A Call To Action

- Reach out to your Senators on the need for a change to the HELP Committee's Draft Legislation before it is introduced
- It is especially important if your Senators are on the HELP Committee to take action
- Even if your Senators are not on the HELP Committee reaching out now is important for two reasons
 - This bill will eventually be on the Senate Floor where we may be working on an amendment
 - Senators talk and making this an issue now puts the issue in their conscience



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Al Franken, Minn.
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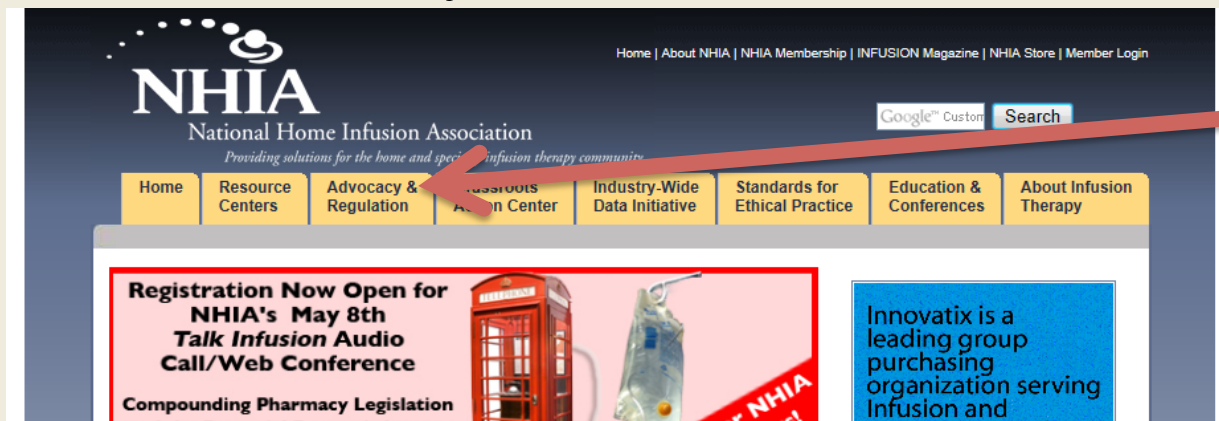
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A Call To Action

- We have provided an easy method for you to reach out to your Senators on the NHIA Website
- A draft letter is prepared for you to send to your Senators
- Use the advocacy tab on our website



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A Call To Action

- Once on the Advocacy page click the action alert box



Providing solutions for the home and specialty infusion therapy community

Home Resource Centers Advocacy & Regulation Grassroots Action Center Industry-Wide Data Initiative Standards for Ethical Practice Education & Conferences About Infusion Therapy

Home > Legislation and Advocacy

NHIA Launches Standards for Ethical Practice

Action Alert
Click Here To Contact Your Senators on Compounding Legislation

Legislation, Regulation and Advocacy



A Call To Action

- Also while you are on our website sign up for our List Serv



The screenshot shows the NHIA website layout. At the top, there are links to various resource centers: HIEC Coalition Resource Center, Medicare Part D Resource Center, HIPAA NPI Resource Center, Reimbursement Resource Center, HIPAA Final Omnibus Rule Resource Center, and Sterile Compounding Resource Center. Below this is the 'NHIA Vital Information' section with links to the 2013 National Coding Standard, INFUSION Magazine, and the NHIA National Definition of Per Diem. A prominent banner reads 'GAO RELEASES REPORT THAT SUPPORTS NEED FOR IMPROVEMENTS IN MEDICARE HOME INFUSION THERAPY COVERAGE' with a link to the report. Another banner mentions 'NPR covers NHIA Educational Exhibition on Capital Hill'. The sidebar on the right, titled 'Tools', lists several resources: NHIA Consultant Network Database, NHIA Home Infusion Provider Member List, NHIA Job Bank, Pharmacy Virtual Tour, NHIA Strategic Plan, Media Relations, NHIA Advertisement & Sponsorship Opportunities, **The NHIA LISTSERV® Message Board** (highlighted with a red arrow), NHIA Staff Directory, NHIA Store, Job Openings at NHIA, and Talk Infusion — The NHIA Membership Forum. A search bar is located at the bottom of the sidebar.



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Wrap-Up – Questions

Question/Answer Session

- To ask a question:
- Press “7” on your touch tone phone

- *As a reminder, this call is being recorded



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Thank You!