



Walking the Halls of Congress: What you need to know for 2018 CCH Hill Day

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Disclosures

Jim Turner, David Pore, and Gary McCrory “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”



Learning Objectives

At the conclusion of this program, the participating pharmacist or technician will be able to:

- Explain the key activity occurring within the pharmacy industry.
- Prepare the three parts of a successful legislative meeting.
- Explain how to be a successful advocate for the pharmacy industry to Congress.
- Describe common pitfalls of Capitol Hill meetings.



Visiting your Representative and Senators in Washington, DC

When visiting the DC office,

- Know that it is different than visiting the Representative or Senator locally in the District or State
- Time is much shorter in Washington, DC.
- The Representative and Senator are usually juggling Committee hearings, meetings with Leadership, Floor Votes, and other meetings with constituents. The schedule is full and it's ever-changing as the day goes on.
- Know going in that Staff will be checking the time, listening for Floor vote buzzers and running to join their bosses.
- In order to convey your message, be clear and concise, prepare, and know **exactly** what you want to say and accomplish.



Visiting your Representative and Senators in Washington, DC

Process for Meetings

- IACP has set up your meetings for you.
- The process for setting up a meeting is always to request the meeting in writing and follow-up with the Scheduler.
- IACP has also put together a packet for you that contains your Ask Documents, background information, and documents to be left behind with Congressional Staff.
- Always follow-up with the Representative, Senator, or Congressional staff that you meet with to say thank you – IACP will help you with this also!

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What to Expect when Meeting with your Representative or Senators in Washington, DC

Meetings in DC are short - Be Clear and Concise

- Always be sensitive to time constraints. Your meeting will only last generally between 15-30 minutes.
- Your **Ask** Documents are designed to outline the issue and make a clear request within a short timeframe.



What to Expect when Meeting with your Representative or Senators in Washington, DC

Meetings in DC are short - Be Clear and Concise

- State upfront who you are, where your pharmacy is located, and why you're visiting.
- Explain your issues and challenges and use examples of where you see concerns on the front lines as much as you can.
- Close with the Asks and Asks Documents.



What to Expect when Meeting with your Representative or Senators in Washington, DC

Make it personal - They want to hear from you!

- Introduce yourself and state where in their district your pharmacy is located.
- If you are a constituent tell them where you're from.
- Share how many patients you serve in that District or State and how many constituents you employ.
- Use examples you have witnessed on the front lines of concerns for patient access to these vital medications and patient safety.
- If you don't know the answer, say that you will have David follow-up after the meeting to get them the answers they need!



Closing the Meeting and Making the Asks

Close every meeting making the official Ask

- In order to keep the meeting concise, appoint a spokesperson prior to the meeting that will make the official Asks. You can have one person in the meeting make all the Asks or split them up so that two different people are each making one Ask.
- Tell the Representative, Senator, or Congressional staffer why this Ask is important to you, compounding pharmacists, and to patients and how their help is needed to preserve patient safety and access to these vital medications.



Tools to Close the Meeting and Make the Asks

Close every meeting making the official Ask

- IACP has designed specific and clear Asks within your packets.
- IACP has also provide background information to help you know the past activities on each issue.
- In addition, IACP has provided documents that can be left behind with the Representative, Senator, or Congressional staffer.



ASK #1 (House): Co-sponsor HR 2871, *The Preserving Patient Access to Compounded Medications Act.*

Background:

- HR2871 is a House bill introduced by Rep. Morgan Griffith (R-VA) and Rep. Henry Cuellar (D-TX).
- HR2871 has 48 bipartisan co-sponsors and has been referred to the House Energy and Commerce Committee.
- HR2871 would clarify the congressional intent behind certain provisions of the Food, Drug, and Cosmetic Act (FDCA) that have been misinterpreted by the FDA in a way that is limiting patient access to compounded medications.



ASK #1 (House): Co-sponsor HR 2871, *The Preserving Patient Access to Compounded Medications Act.*

Key Provisions of HR2871:

- Clarify that “office-use” compounding by 503A pharmacies where authorized by state law is not a violation of the Food, Drug, and Cosmetics Act (FDCA) and does not make a pharmacy a drug manufacturer.
- Clarify that the MOU between FDA and the states on interstate **distributions** of compounded medications does not include patient-specific dispensing.
- Clarify that all ingredients with a USP or NF Dietary Supplement Monograph are acceptable bulk substances for compounding.
- Clarify that state licensed and compliant compounding pharmacies receive the same records and registration exemptions granted to compliant retail pharmacies under the FDCA.
- Require the FDA to go through the notice and comment rulemaking procedure when enacting policies pursuant to the DQSA rather than issuing “Guidance for Industry” documents that do not have the weight of law and often do not adhere to the statute.



ASK #1 (Senate): Introduce a Senate Companion to HR 2871, *The Preserving Patient Access to Compounded Medications Act*.

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- Require the FDA to go through the notice and comment rulemaking procedure when enacting policies pursuant to the DQSA rather than issuing “Guidance for Industry” documents that do not have the weight of law and often do not adhere to the statute.



ASK #2 (House): Sign on to the letter to FDA Commissioner Scott Gottlieb on the make-up of the Pharmacy Compounding Advisory Committee (PCAC).

Background:

- The PCAC makes recommendations to the FDA on whether or not to allow specific ingredients to be used in compounding.
- These recommendations are used by FDA to establish a “positive list” as well as a “demonstrably difficult to compound” list of approved and unapproved substances.
- There are currently 12 voting members and 2 non-voting members on the PCAC (one of whom is a compounding pharmacist). None of the voting seats are held by compounding pharmacists and there is little to no representation on the committee representing providers and patients who use and depend on compounded medications.
- FDA will be filling as many as four voting position vacancies on the PCAC this year.



ASK #2 (House): Sign on to the letter to FDA Commissioner Scott Gottlieb on the make-up of the Pharmacy Compounding Advisory Committee (PCAC).

Key Provisions from PCAC Letter:

- The FDA would benefit from having the unique perspective of compounding pharmacists with experience in patient-facing community settings, and from other members with current knowledge of the importance and use of compounded medications.
- There is currently a noticeable absence of expert perspective on the PCAC that a voting member who is compounding pharmacist would provide.
- Upcoming vacancies for voting positions on the PCAC should be filled with compounding pharmacists with recent, relevant experience in community pharmacy settings, and by patient representatives and providers with current experience with compounded medications.



ASK #2 (Senate): Contact the FDA regarding the make-up of the Pharmacy Compounding Advisory Committee (PCAC).

Background:

- The PCAC makes recommendations to the FDA on whether or not to allow specific ingredients to be used in compounding.
- These recommendations are used by FDA to establish a “positive list” as well as a “demonstrably difficult to compound” list of approved and unapproved substances.
- There are currently 12 voting members and 2 non-voting members on the PCAC (one of whom is a compounder), however, the committee lacks adequate representation of individuals with contemporary patient-facing compounding expertise and none of the voting members are compounding pharmacists.
- FDA will be filling as many as four voting position vacancies on the PCAC this year.



ASK #2 (Senate): Contact the FDA regarding the make-up of the Pharmacy Compounding Advisory Committee (PCAC).

Key Points for FDA Communications on PCAC:

- The FDA would benefit from having the unique perspective of compounding pharmacists with experience in community settings, and of providers or patients with current experience with compounded medications.
- There is currently a noticeable absence of expert perspective on the PCAC that a voting member who is compounding pharmacist would provide.
- Upcoming vacancies for voting positions on the PCAC should be filled with compounding pharmacists with recent, relevant experience in patient-facing community pharmacy settings, and with providers or patients knowledgeable with the use of compounded medications.



Provide Feedback to IACP

Take notes during your meetings and share feedback with IACP!

- There will be a closing debrief after the Hill visits where you will have the opportunity to share how your meetings went and what you learned on a feedback form.
- These feedback forms are instrumental to providing IACP lobbyists like Cynthia and David with information as to which offices need more information, where additional meetings are needed, and where follow-up is needed on the Asks.
- We found one of our biggest Congressional champions, and you heard him speak to you this CCH, through the feedback forms for last year's CCH!

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Keep in Mind

- Know what to expect – time is short so be clear and concise.
- Make it personal! Congress wants to hear from you and how your patients will be impacted!
- Close the meeting with the Asks.
- Rely on the packet that IACP has put together for you. It contains your background information on the issues, the actual Ask documents and the additional leave behind documents to assist the Congressional staffers.
- Take notes and provide feedback to the IACP lobbyists team.
- Follow-up through IACP with the Congressman or Senators you meet with to say thank you.

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THANK YOU!

ONWARD TO THE HILL!

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