

Government and Regulatory Affairs – Consent Agenda Items

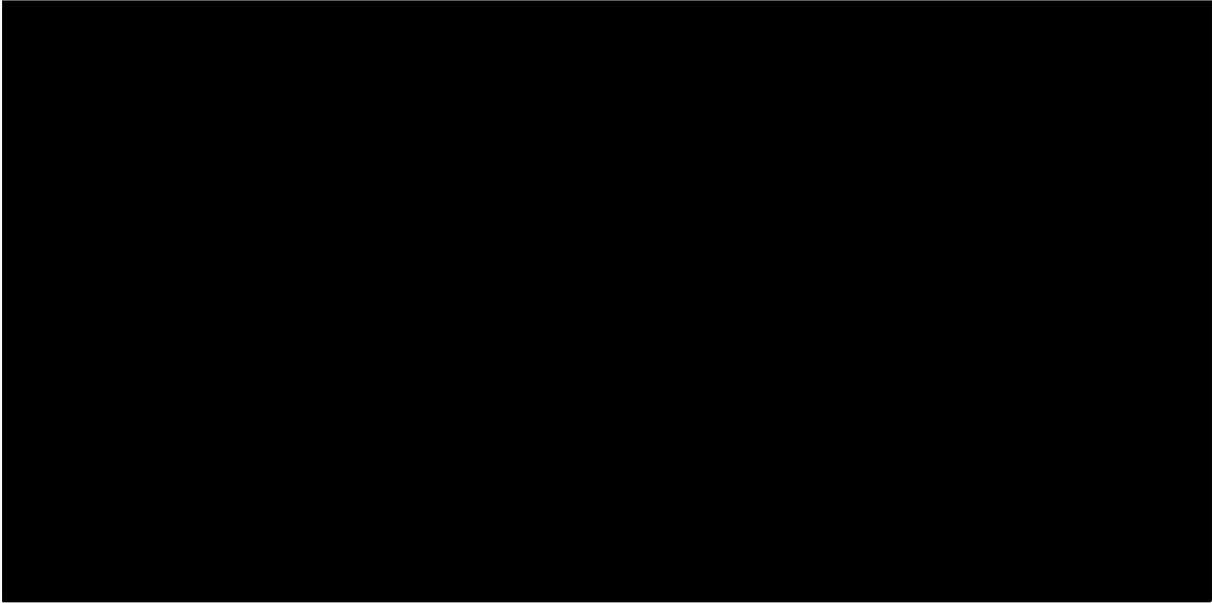
Protecting Pharmacy Compounding Practice

- IACP Political Action Committee (PAC) Organization and Activities
- Lobbyist Selection & Results
- Capitol Hill Activities
 - Senator Kennedy – 503A Resurrection; Briefing with Rep. Waxman
 - Senator Grassley – Letter to CMS, FDA regarding inhalation compounds; IACP-APhA Response
 - USP/PCAB Appropriations Request
- Legal & Litigation
 - Midland – Activity, IACP Role
 - FDA Inspection Revision, Facts Don't Fit Revision
 - BET Consent Decree
 - SC Federal District Court – Dr. James Shortt, Congaree Pharmacy Adverse Event
 - Iowa – Gar Houck OTC compounding
- Federal Agencies
 - FDA FOIA
- USP Chapters
 - IACP's <797> comments
 - USP <1163>
- State Regulation
 - Florida
 - Letter to North Carolina Board of Pharmacy on Behalf of Triangle Compounding Pharmacy
 - Recent State Board Activities
 - Letter to all State Boards of Pharmacy regarding Midland decision
- Pharmacy & Medical Group Outreach
 - American Medical Association (AMA) Resolution on compounding
- Quality Initiatives
 - Adverse Event Reporting



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IACP001724



Iowa State Court – Gar Houck v. Iowa Board of Pharmacy Examiners, OTC Compounding

IACP member Gar Houck of Houck Drug Co. in Clear Lake, Iowa has petitioned IACP for legal assistance regarding a disciplinary action by the Iowa Board of Pharmacy against the pharmacy.

On March 13, 2002, the Board of Pharmacy received a complaint about a medication that Houck Pharmacy compounded for a patient. Upon investigation, the Board investigator found that the pharmacy had compounded a nasal suspension (using non legend drugs) for the patient without a prescription – or compounded an OTC medication for a patient. The Board brought a case against the pharmacy regarding this matter and other deficiencies observed. The Board found the pharmacy to have violated Iowa laws and regulations and fined the pharmacy, as well as sentenced the pharmacy license to three years of probation. Houck Pharmacy appealed the ruling to the Iowa district court, which denied the appeal. Houck Pharmacy has indicated intent to appeal the case to the Iowa Supreme Court and has asked IACP for assistance in the final appeal.

The case rests on Iowa laws and regulations regarding pharmacy practice and the Iowa Board of Pharmacy's regulation of OTC compounding. State Boards of Pharmacy and state legislatures have clear authority to determine standards for pharmacy practice, including OTC compounding. IACP continually proselytizes the role of the state boards of pharmacy as the appropriate entity to regulate the profession, as opposed FDA or another body.

IACP has suggested that Mr. Houck engage the Iowa Pharmacy Association, as the local association is intimately familiar with state laws and regulations (Mr. Houck is unhappy with the local association and has speculated that they will not assist him). IACP traditionally focuses its legal attention and investments at the federal regulation, on cases that are broad in scope and have potential to impact the entire profession. Copies of Houck Pharmacy's filings and subsequent decisions are available for Board review upon request.



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STATE REGULATION

- **IACP Comments on Florida Sterile Compounding Regulations**
- **Letter to North Carolina Board of Pharmacy on Behalf of Triangle Compounding Pharmacy**
- **Recent Activity by Boards of Pharmacy**
- **Letter to all Boards of Pharmacy Regarding Midland decision**

IACP Files Comments with Florida Board on Proposed Sterile Compounding Regulations
The Florida Board of Pharmacy has been working to update its sterile compounding regulations. In August, IACP received a hearing notice and a request for comments on the draft regulations. IACP sent a copy of the draft regulations and a meeting notice to all Florida members at that time. IACP also prepared initial comments on the draft regulations. Our initial comments addressed Florida's incorporation of an in-revision version of USP <797> into the draft regulations. IACP's comments also suggested that language consistent with IACP's labeling recommendations be incorporated into the proposed regulations. The Board of Pharmacy is scheduled to consider the final draft regulations at its meeting on October 3. IACP will be reviewing the final draft regulations and filing comments where appropriate.

Letter to North Carolina Board of Pharmacy on Behalf of Triangle Compounding Pharmacy

IACP recently cautioned the North Carolina Board of Pharmacy against relying on certain factors when considering possible disciplinary action against Triangle Compounding Pharmacy in relation to an adverse event in 2005 (lidocaine overdose caused patient death). The letter emphasized the necessity for and value of compounding and cautioned the Board against relying on volume as an indicator of proper v. improper compounding practice. The letter also highlights the physician's responsibility in prescribing and administering an office use preparation. (See Attachment 9 for a copy of the letter).

Recent Activity by Boards of Pharmacy

The following compounding-related activities have been reported to IACP in recent months. In several of these cases, IACP is working to review regulations and write comments where appropriate.

- **Florida:** Draft sterile regulations to be reviewed by Florida Board of Pharmacy during October 3, 2006 meeting.
- **Maryland:** Technician regulations approved by the Board on September 20, 2006. Enter regulatory review cycle on October 10, 2006.
- **Minnesota:** Revision to pharmacy regulations, including sterile and nonsterile compounding standards. The Board intends to adopt the rules without a hearing, but if 25 or more persons petition the Board to hold a hearing prior to November 1, a hearing will be held.
- **Nevada:** Substantial revisions to sterile and nonsterile compounding regulations are being considered by the Board of Pharmacy. The Board has two hearings scheduled – one held on September 7 in Reno and the other scheduled for October 25-26 in Las Vegas.
- **New Mexico:** Final draft of non-sterile compounding regulations submitted for regulatory filing on June 5th (a hearing was previously held on the draft regulations in March).



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- **Texas:** The Texas Board of Pharmacy's Task Force on Compounding met in July to consider additional revisions to the sterile compounding regulations to reflect changes in the proposed USP <797>. The Task Force was scheduled to report its recommendations at the Board's August meeting. Office use regulations were also expected to be discussed at that meeting.

Letter to State Boards of Pharmacy Regarding Midland Decision

Following the Midland decision, IACP sent a letter to every state board of pharmacy informing them of the decision with particular emphasis on the legality of compounding from pure pharmaceutical ingredients for animals. This is in response to the FDA letter to boards of pharmacy in spring 2004 in which FDA asked for state board cooperation in enforcing that compounding from pure pharmaceutical ingredients for animals is illegal. See also page R-9.



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