



Competent Compounding

July 2010

Kenny Walkup, RPh, FIACP

As I reported in my last newsletter I was heading to Washington DC for the annual Compounders on Capital Hill meeting. This meeting is conducted by the International Academy of Compounding Pharmacists (IACP). It consists of two days of educational sessions and a third day of congressional appointments. That is our time to lobby our Senators and Congressman on issues important to pharmacy compounding. Our lobbying efforts this year related to the FDA's current stance on veterinary compounding. Below is a press release from Dave Miller, CEO of the International Academy of Compounding Pharmacists. (I have made editorial comments in blue to add some context to the press release).

"Our members requested that the U.S. Senate convene oversight hearings to investigate the legislative intent of the Animal Drug Use Control Act of 1994 (AMDUCA) and the FDA's resultant jurisdiction over veterinary compounding from bulk ingredients," said IACP Executive Vice President David Miller.

It is the stance of the FDA that it is illegal for a pharmacy to compound for an animal from a bulk jar of ingredients. However, that same body says it is OK to do the same for human compounding.

"These visits to Congress came at a particularly critical time for compounding pharmacies across the country and for the patient which they serve. Every person who joined us on Capitol Hill and those thousands of patients and prescribers who called and wrote their members of Congress were vital to ensuring that our voice was heard," said Miller.

IACP has approached both the Senate and the House of Representatives repeatedly to resolve this dispute. Members of both chambers have written the Food and Drug Administration (FDA) on numerous occasions asking for an explanation over the agency's issuance of a 2003 Compliance Policy Guideline (CPG) that IACP believes exceeds the legislative intent found in AMDUCA.

CPGs are used by the FDA to give guidance to the FDA inspectors on how to enforce their policies. More to follow on that.

Despite promising certain specific actions, the FDA has yet to act. The FDA's refusal to respond in a timely and appropriate manner to both constituent and Congressional inquiry is well documented. IACP continues to request Senate Oversight Hearings to resolve this issue.

In July of 2003, without warning or providing opportunity for public review and comment, (providing public review and comment has long been the way of handling the publishing of CPGs) the FDA published a new Compliance Policy Guideline (CPG) concerning veterinary compounding, in which compounding from bulk ingredients for nonfood animals was forbidden. CPGs are technically internal guidelines, not laws, but they are enforced by the FDA as if they were law. The CPG significantly overstepped the legal jurisdiction of the FDA outlined by Congress in AMDUCA and subsequent laws.

Subsequently in June of 2004, in response to inquiries from pharmacists and constituent patients, more than 70 members of Congress (including Senator Carl Levin and Senator Debbie Stabenow) wrote the FDA, requesting either the withdrawal or the revision of the CPG after providing for an appropriate public comment period. The FDA responded by assuring IACP that a new CPG would be issued and subjected to public comment. The FDA did neither.



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In June of 2005, after one year of inaction on the part of the FDA, 113 members of Congress signed letters requesting justification. The FDA never withdrew and released the CPG for appropriate review and public comment.

*Most recently in April of 2010, after several years of status quo, the FDA filed a permanent injunction against a compounding pharmacy in Ocala, Florida, for compounding from pure drug chemicals. **In plain English, they closed down this pharmacy for compounding for animals from bulk containers.** As a result, this dispute is no longer rhetorical. Patients' lives and the pharmacy profession will be affected. Congressional oversight hearings must be held to clarify the FDA's jurisdiction and action over veterinary compounding." **I agree whole-heartedly.***

I am happy to report that I had the opportunity to meet with the Health Legislative Aides from the offices of Senators Levin and Stabenow and Congressmen Dingle and Rogers. All were very receptive to listen to our needs. Now I need your help. Call your Michigan Senators today and urge them to have these oversight hearings on the FDA. They signed this document once before and it is imperative that they do so again.

On a personal note, the highlight of the meeting for me was my being awarded Full Fellowship into the International Academy of Compounding Pharmacists at their luncheon awards ceremony on Sunday. From the IACP website: "the Fellowship Program distinguishes pharmacists who are exemplary in their professionalism and commitment to the practice of pharmacy compounding". There are a total of 64 Full Fellows recognized internationally by the academy. There were two of us this year that were given this award.

Kenny R Walkup, Jr., RPh, FIACP

Owner, Specialty Medicine



This is a picture of Kenny on the steps United States Capital.



Kenny receiving his Fellowship plaque at the IACP banquet.



Michigan pharmacist Dave Miller, Senator Debbie Stabenow and Kenny Walkup in Senator Stabenow's Washington DC office.



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