Memorandum

To: Board of Directors
From: L.D. King
Date: October 8, 2003
RE: Legislative Strategy for Veterinary Compounding

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We have been thinking through a possible legislative fix for compounding for animals. Our current thought is to identify a key Senator who can buy into our issue wholeheartedly. The Senator would attach a "midnight rider" to a bill that is assured of passing. The rider or amendment would essentially clarify that pharmacists may compound from bulk drug products for non-food producing animals. This is a similar approach that Senator Bond took when attaching the FDA advisory committee amendment ot the Medicare legislation.

Optimal Senator: Judd Gregg (R-NH), Chairman of Health Committee
Groundwork: November 15- February
Target: After February, 2004 (must find an appropriate vehicle to attach bill)

The primary problems with a public widespread legislative campaign are that it can be very costly and timely. More importantly, it allows powerful stakeholders (including FDA, AVMA, DOA, Senator Bond, etc) to amend the legislation to our dismay.

Attached is an excerpt from a memo that I wrote to the executive committee regarding the option to pursue legislation for compounding. This discussion is tailored to human compounding. However, many of the concerns listed carry over if IACP were to pursue a widespread public legislative campaign. Primary concerns: a public campaign

EXCERPTS FROM A SUMMER 2003 MEMO RE IACP LEGISLATIVE OPTIONS

There is appears to be growing support for IACP to introduce legislation similar to legislation IACP introduced in 1994:

IACP's 1994 PROPOSED LEGISLATION

OCTOBER 7, 1994
Mr. BREWSTER (for himself and Mr. DELAY) introduced the following bill;

To guarantee the ability of licensed pharmacists to conduct the practice of pharmacy compounding and to ensure their right to the necessary supply of bulk drug products, subject to applicable State and Federal laws.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the ''Pharmacy Compounding Preservation Act of 1994''.

Amend section 210(gg) of the Food, Drug and Cosmetic Act (21 U.S.C. 321(gg)): ''notwithstanding any other provision of law, the provisions of this Act do not apply to licensed retail pharmacies that compound drugs in conformance with applicable local laws regulating the practice of pharmacy and medicine. The provisions of this Act do not apply to bulk drug products that are intended to be used by pharmacies for compounding, except to the extent that such provisions relate directly to the purity and quality of such bulk drug products.''

However, this legislation bears little resemblance to that which was passed eventually passed in 1997 as part of the Food and Drug Administration Modernization Act (FDAMA) and became 503A of the Food, Drug and Cosmetic Act (FDCA). 503A restricted pharmacy compounding in the following ways:

1) 503A(a)- "identified" individual patient language threatened office stock compounding.
2) Limited bulk drug substances for use in compounding to those FDA-approved drugs (orange bulk and approved bulk substances—positive list) and USP/NF monograph bulk drugs.
3) Classes of drug products deemed demonstrably difficult to compound—therefore illegal to compound (sterile drugs [unless USP1206 was followed to the letter], metered does inhalers, transdermal matrix patches). Proposed additions to demonstrably difficult at the time of the Supreme Court case included classes of commonly compounded products: narrow-therapeutic drugs, enteric coated drugs, and flavored antibiotics.
4) Limited interstate compounding to 5% unless the state entered into a memorandum of understanding developed by NABP and FDA. (The proposed MOU lifted the percentage to 25% regardless of the validity of the compounding)
5) Created a list of drug products prohibited for use in compounding. FDA could add a product to the list at their discretion.

The legislation also created an advisory committee on pharmacy compounding to advise FDA regarding pharmacy compounding regulations (list of bulk substances to be used, not used, MOU, demonstrably difficult, definition of inordinate amounts, etc). This committee was completely stacked against us and turned out to be merely a rubber stamp for FDA. They forced Loyd Allen to be a non-voting member because of his alleged conflict by working for IJPC. We had only one practicing compounding pharmacist and one NCPA member. Their alleged neutral pharmacist member was Sarah Sellers (have you read her in the press??). Randy Juhl—chair of the committee has made some disparaging remarks toward compounding. They readily agreed with FDA's proposal that classes of drugs including sterile drugs could be named demonstrably difficult. We had virtually no chance to argue for drug substances such as cisapride which FDA proposed to add to the list of substances prohibited for use in compounding. The committee squashed any argument we could bring up. Further, PhRMA which had a couple of representatives was arguing strongly at that time that we should not be allowed to import bulk substances from Europe without testing for mad-cow disease. I could literally fill a few pages on the horror of FDA's advisory committee on compounding.

IACP has shelves of binders on evidence submitted to the committee—most of which probably ignored. As a result of a huge amount of work and multiple trips to D.C., we were able to get a few drug substances added to the positive list.

Meetings to determine positive list drugs turned into IACP spending enormous time and energy to defend each chemical submitted. We even had to obtain approval for salt forms of approved drugs (e.g. metronidazole benzoate). Such a process severely hampers innovation that has been so beneficial to pharmacy compounders.

503A did exempt pharmacy compounding from NDA's and GMP's, but the Act also gave clear legal authority to FDA over pharmacy compounding. The act gave clear legal authority to FDA to write regulations for pharmacy compounding. Because of this, NCPA and many IACP members eventually thought we gave too much up and the legislation was detrimental. When we began to see how FDA began to implement this law and how FDA used the Pharmacy Advisory Committee to support FDA's blatant abuse of authority, many more—including our attorney, began to question whether the legislation did more harm than good. This is why we did not argue strongly for severability of the advertising restrictions at the Supreme Court. We theorized that the Court striking down the legislation may be beneficial if the Court rejected FDA's theory that the legislation legalized compounding. We therefore used our entire brief to refute FDA's argument that the 1938 Food, Drug, and Cosmetic Act made compounding illegal.

Because of the Supreme Court case FDA does not enjoy clear legal authority over pharmacy compounding. The IACP Board following the Court's decision in 2001 decided not to pursue new legislation (the decision was made in extensive, documented consultation with PCCA and other key stakeholders and key members). This decision is a fundamental strategic issue; however, this was not an objective listed in our strategic planning session nor do we have any one year goals regarding new legislation for human use pharmacy compounding.

PROBLEMS OF NEW LEGISLATION

First, neither Howard Hoffman nor Jeff Gibbs believes legislation would be a wise move. Hoffman believes the FDA has no legal authority in pharmacy and legislation would doubtless give them that authority.

The key question is how can we assure ourselves that legislation identical to that proposed by IACP in 1994 will not become legislation eventually passed in 1997?

The environment in 1994 was very favorable. Pharmacy compounding had an exemplary track record. There was only one reported case in Pennsylvania in which a hospital pharmacy dispensed contaminated eye drops that resulted in adverse affects including blindness for a patient. There were no documented patient deaths.

Today, the risks of pharmacy compounding are well documented. There are multiple cases of adverse affects and documented patient deaths due to pharmacy compounding.

There are multiple documented cases of contamination. There are multiple cases of super and sub potent compounded medications dispensed., Kansas City Star did an extensive series on pharmacy compounding bringing into question potency, contamination, cases of fraud, lack of education and training, lack of state regulation, technician and pharmacist incompetence, lack of scientific validity, false and misleading claims, and adverse affects to patients. Finally, FDA's study on pharmacy compounding shows an alarming rate of sub-potent medications, providing our critics powerful ammunition in light of Robert Courtney who intentionally dispensed thousands of subpotent medications to patients. Regardless of the accuracy of this information or lack of perspective, there is no doubt that all of this information will be carefully packaged and repeated to Congressmen over and over throughout a legislative process. Pharmaceutical manufactures and FDA will use their resources to ensure Congress that these problems as documented will continue and worsen unless FDA is given clear authority in pharmacy compounding.

In addition, we have some new enemies in Congress. Senator Kit Bond-MO has expressed grave concern over pharmacy compounding following Courtney. He has had meetings of stakeholders to debate a federal end-product testing program for all pharmacy compounded medications. IACP, with a coalition of pharmacy groups, strongly opposed the concept and sought to educate Bond on the fallacy thereof. However, Friday, Bond amended a Medicare bill to re-create the FDA pharmacy advisory committee on compounding!! This can't be a good thing. Congressmen Henry Waxman has scrutinized pharmacy compounding since the Wall Street Journal report on nicotine lollipops.

In my direct conversations with FDA which started under Ray Moreno's presidency, I have seen a shift in FDA's rhetoric. Prior to September 11, 2001, FDA was very eager to pursue legislation to regain legal clarity of pharmacy compounding following the Court case. I believe that FDA thought this was a realistic goal and hastily issued a CPG to indicate that FDA was not going to allow there to be a regulatory vacuum for pharmacy compounding.

After September 11, FDA appears less and less able and willing to pursue legislation on their own. FDA has been overwhelmed in new bioterroism measures implemented and Congress concern over the virtual total lack of oversight on the import of food and drugs into the US. There is even written documentation coming from the Agency that pharmacy compounding in taking a lower priority. This trend was seen further with the arrival of FDA commissioner Mark McClelland. I have heard McClelland speak at length to NCPA pharmacists on pharmacy related issues and never once bringing up pharmacy compounding. This is in stark contrast to former commissioner, David Kessler, who seemed to almost have a personal agenda against compounding and personally presented the first official FDA compliance policy guide on pharmacy compounding at the APhA annual meeting in California in 1992. McClelland has other priorities that do not seem to include compounding. After McClelland took over, Horwitz and Axelrad told Levesque and myself that pharmacy compounding had once again lowered in priority and that the bureaucratic process (must get approval from top officials at FDA and then go through the chain of command at Health and Human Services) made the prospect of FDA introducing legislation virtually impossible.

This leads to the following possibility for consideration. Axelrad and Horowitz speak to IACP regarding the desirability of introducing legislation. We then react in fear and propose legislation ourselves to be "proactive". Does IACP's legislation play directly into FDA's hands. FDA officials could easily get authority to act on legislation if there were legislation proposing to eliminate or limit their authority. (Bureaucracies become suddenly very efficient in such cases). Suddenly we have an amended bill that at best looks similar to 503A. What have we done? Can we control the bill with pharmaceutical manufactures supporting millions of dollars to Congressional campaigns? Not only this, but we would face opposition from within (Western States pharmacies) and from without (NCPA is opposed to seeking new legislation).

Could we get consensus for proposed legislation? I believe that there are those that would oppose us even introducing the 1994 bill as it would provide a vehicle for the FDA to amend and get legal authority again. But if we were to introduce a bill, what types of things could be negotiated on? What types of restrictions or requirements could we agree to? We have had difficulty agreeing on any concepts beyond:

Triad relationship
Don't sell at resale
Don't make exact copies of commercially available drugs

It should be noted that if FDA or someone else proposed legislation on pharmacy compounding that we are opposed to, it is much easier to kill legislation than to pass it. Passing legislation takes an enormous amount of resources, and a resource assessment is critical before any legislation is proposed. Rough estimate of additional costs:

$25,000 per month legal and lobbying fees

$50,000 new employee focused on federal legislation. (Current regulatory affairs coordinator has full-time work with Accreditation, state and international regulations. Our last full-scale legislative effort took three years. Total rough estimate of additional cost is more than $1 million. Obviously, we would need an accurate assessment.