THE TRUTH ABOUT COMPOUNDING FOR ANIMALS FROM BULK SUBSTANCES

RESPONSE TO THE ANIMAL HEALTH INSTITUTE: THE FOOD DRUG & COSMETIC ACT (FDCA) DOES NOT PROHIBIT COMPOUNDING FROM BULK SUBSTANCES FOR USE IN ANIMALS.

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SUMMARY

The Animal Health Institute (AHI) is a trade group representing pharmaceutical manufacturers[i] with an interest in veterinary medicine. Despite its claim to support what it calls "legitimate animal drug compounding," it has long opposed many uses of compounding for major species, such as dogs, cats and horses, in modern veterinary practice. The organization espouses the viewpoint that using bulk ingredients to compound medications for use in animals is "illegal." On June 4, 2013, in an Open Letter to Veterinarians, the AHI asserted:

> *"In recent days and weeks veterinarians have received communications from compounding pharmacies regarding Congressional consideration of legislation on drug compounding. We, the Animal Health Institute (AHI), have been prominently mentioned and mischaracterized in those communications."*

At the time of its Open Letter to Veterinarians, the AHI also issued a tortured legal analysis to support its claim that compounding from bulk substances for animal use is not legal. It is on this false premise that the AHI is able to claim that the original version of Senate Bill 959 ("The Pharmaceutical Compounding Quality and Accountability Act") …

> *"… is more permissive than current law. It would legalize a certain amount of needed compounding from bulk active ingredients. It would do nothing to restrict current legal compounding–the pharmacy manipulation of approved drugs under a veterinary prescription to meet the needs of a particular patient. It would also provide a mechanism for medically necessary compounding from bulk substances where there are no approved products that will meet a medical need. We have asked Congress to legitimize necessary compounding from bulk substances by directing FDA to create and maintain a list of products or substances that can be*

compounded from bulk while making it clear that all other, non-listed compounding from bulk remains illegal."

AHI supports policies that would dramatically re-shape modern veterinary practice, by reducing the number of active ingredients available for compounded medications to a "positive list" of drugs that may be compounded, which would be extraordinarily restrictive compared with current practices.

The AHI also continues to hold the self-serving, scientifically untenable and ultimately dangerous point of view that all compounded medications must be made from the "approved drugs" they manufacture. In this, the AHI demonstrates that its motives are for its members' profits, not animal health. (For a detailed and accurate discussion about the need to use of active pharmaceutical ingredients in compounding for animals, see *What are Bulk Ingredients and Why are they Necessary in Compounding*."

THE COURT REJECTED FDA'S STATEMENT OF LAW

The trial court in *United States v. Franck's Lab Inc.*[1] is the *only* court that has considered whether the FDA can prohibit a pharmacy from compounding animal drugs from bulk. Arguing before this court, FDA took the position that its power to prohibit compounding from bulk substances comes from the plain language of the Food, Drug and Cosmetic Act (FDCA), as originally enacted in 1938. FDA claimed that animal compounds are new animal-drugs, subject to new animal-drug approval; as such, FDA concluded that it could prohibit compounding from bulk. **The *Franck's* court rejected the FDA's position**. The court held that the FDCA does *not* permit FDA to stop a state-licensed pharmacy from compounding animal drugs from bulk pursuant to a valid veterinary prescription.[2]

FDA agrees that the *Franck's* court is the only court to have considered this issue. In *Franck's*, "FDA acknowledge[d] that this is the first time it has sought to enjoin a state licensed pharmacy from bulk compounding of animal medications."[3] To place the issue squarely before this court, FDA took a "bright-line position that *any* compounding of animal medications from bulk substances violates its enabling statute … [FDCA] … even when conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription."[4] The only time a court has considered FDA's statement of law—that FDA can prohibit animal compounding from bulk based on the plain language of the FDCA—its position was *rejected*.

[1] *816 F.Supp.2d, (M.D. Fla. 2011)*
[2] *Franck's*, 816 F.Supp.2d at 1235-56
[3] *Franck's*, 816 F.Supp.2d at 1214
[4] *Id*

NO FEDERAL COURT OF APPEALS HAS CONSIDERED THIS ISSUE

No federal court of appeals has considered whether the FDA can prohibit a state-licensed pharmacy from compounding animal drugs from bulk. The *Franck's* decision never reached the court of appeals. The pharmacy sold its assets, ceased to function as a pharmacy, and the appeal was subsequently dismissed as moot. (*United States v. Franck's.*[5])

FDA and others, including the AHI, claim that three federal court of appeals have held that FDA can prohibit a state-licensed pharmacy from compounding animal drugs from bulk. *None* of these cases made this determination, as FDA prohibiting compounding animal drugs from bulk was not the issue before these appellate courts.

MEDICAL CENTER V. MUKASEY[6]

This court focused heavily on human compounding with an extensive analysis of FDAMA. It briefly discussed animal compounds, but only in the context of the Animal Medicinal Drug Clarification Act ("AMDUCA").[7] FDA does not believe that AMDUCA gives it the authority to prohibit animal compounding from bulk.[8] FDA takes the position that its authority to prohibit compounding from bulk comes from the original FDCA and the creation of the new-drug approval process, a position subsequently rejected in the *Franck's* decision. Thus, *Medical Center* does not support FDA's position that it can prohibit animal compounding from bulk based on the plain language of the original FDCA.

UNITED STATES V. 9/1 KG. CONTAINERS[9] AND UNITED STATES V. ALGON CHEMICAL INC.[10]

Neither of these cases discussed pharmacists, the practice of pharmacy, or FDA's ability to regulate pharmacy practice. In both cases, FDA brought enforcement actions against suppliers of bulk ingredients to prohibit them from providing unapproved bulk ingredients to veterinarians for use in compounding.[11] This distinction is important, based on later developments in United States Supreme Court jurisprudence.

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[5] Case No. 11-15350 Dkt. 6692502-2 (11th Cir. Oct. 18, 2012)

[6] 536 F.3d 383, (5th Cir. 2008)

[7] *Medical Center,* 536 F.3d at 394 and 407-8

[8] *Franck's*, 816 F.Supp.2d at 1234

[9] 854 F.2d 173, (7th Cir. 1988)

[10] 879 F.2d 1154, (3d Cir. 1989)

[11] *9/1 Kg. Containers*, 854 F.2d at 175; *Algon*, 879 F.2d at 1155

Both *9/1 Kg.* and *Algon* predate two seminal United States Supreme Court decisions, *FDA v. Brown & Williamson Tobacco Corp.*[12] and *Thompson v. Western States Medical Center*.[13]

- In *Brown & Williamson*, the Supreme Court recognized that a literal reading of the FDCA should be rejected when it goes outside of original congressional intent.[14]
- In *Western States*, the Supreme Court specifically recognized the longstanding historical importance of compounding pharmacy. It acknowledged that forcing compounds through new drug approval would eliminate compounding pharmacy and leave patients who have no alternative without medication.[15]

Under these two precedents, a literal reading of the FDCA that eliminates a longstanding practice of compounding pharmacy, like compounding animal drugs from bulk, should be rejected as outside of original congressional intent.

THE FDCA DOES NOT GIVE FDA AUTHORITY TO PROHIBIT ANIMAL COMPOUNDING FROM BULK

Any statutory analysis of the FDCA must be read against the backdrop of the rules of statutory interpretation. The *Franck's* court, the only court to consider this issue, rejected FDA's claimed authority to prohibit compounding from bulk for animal drugs based on three basic principles of statutory interpretation:

(1) Congress will not hide an elephant in a mouse-hole, i.e., Congress does not delegate decisions of economic and political significance to an agency in a vague or cryptic fashion;

(2) Congress must speak clearly when it intends to displace traditional state regulation of a particular practice (i.e., the state regulation of pharmacy practice); and

(3) If a statute carries criminal penalties, it must be interpreted in favor of the defendant to avoid punishing conduct more severely than Congress intended.[16]

The *Franck's* court concluded that Congress would *not* hide the elephant—its intention to regulate pharmacy compounding—in the mouse-hole of the new-drug approval

[12] 529 U.S. 120, (2000)

[13] 535 U.S. 357, (2002)

[14] *Brown & Williamson* , 529 U.S. at 131-33

[15] *Western States*, 529 U.S. at 369-70

[16] *Franck's*, 816 F.Supp.2d at 1235-56

process; FDCA does not clearly show Congressional intention to displace traditional state regulation of pharmacy practice; and as the FDCA carries criminal penalties, FDA's read would punish conduct more severely than Congress intended.[17]

END NOTES

[i] **AHI Members**

- Abbott Animal Health
- Bayer Healthcare LLC, Animal Health Division
- Bioniche Animal Health USA
- Boehringer Ingelheim Vetmedica, Inc.
- Colorado Serum Company
- ECO Animal Health
- Elanco Animal Health, A Division of Eli Lilly and Company
- Merck Animal Health
- Merial Limited
- MVP Laboratories, Inc.
- Novartis Animal Health US, Inc.
- Phibro Animal Health Corporation
- Virbac Corporation
- Zoetis

Affiliate Members

- AlcheraBio LLC
- Animal Clinical Investigation
- Aratana Therapeutics Inc.
- Benchmark Biolabs, Inc.
- Biotechnical Services, Inc.
- Mars Veterinary
- MPI Research
- Nestlé Purina PetCare Company
- VetPharm, Inc.

[17] *Franck's*, 816 F.Supp.2d at 1235-56