FILED

2012 JUL 19 PM 3:20

CLERK, US DISTRICT COURT
MIDDLE DISTRICT OF FL
OCALA FLORIDA

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

THE CINCINNATI INSURANCE COMPANY,

CASE NO.: 5:12-cv-406-oc-10PRL

Plaintiff,

v.

QUORUM MANAGEMENT CORP. a/k/a QUORUM MANAGEMENT COMPANY, JUAN MARTIN NERO, GUILLERMO CASET, NICHOLAS ESPAIN, ANTHONY J. CAMPBELL, DIAMOND STATE INSURANCE COMPANY, a/s/o QUORUM MANAGEMENT CORP.,FRANCK'S PHARMACY, INC., and FRANCK'S LAB, INC.,

Defendants.
_____/

COMPLAINT FOR DECLARATORY JUDGMENT AND FURTHER RELIEF

Plaintiff The Cincinnati Insurance Company, by counsel, sues Defendants, Quorum Management Corp. a/k/a Quorum Management Co., Juan Martin Nero, Guillermo Caset, Nicholas Espain, Anthony J. Campbell, Diamond State Insurance Company a/s/o Quorum Management Corp., Franck's Pharmacy, Inc., and Franck's Lab, Inc., and alleges:

JURISDICTION AND VENUE

1. This is an action for declaratory judgment, and for such further relief as may be necessary or proper, pursuant to 28 U.S.C. §2201(a), to declare the rights, status and legal relations of Plaintiff and Defendants under insurance policy contracts.

2. The Cincinnati Insurance Company (Cincinnati) is a corporation organized and existing under the laws of Ohio, with its principal place of business in Cincinnati, Ohio.

3. At all material times, Cincinnati was engaged in the business of issuing insurance policies to indemnify against various, specified risks, and authorized by the Florida Department of Financial Services to conduct business in Florida.

4. At all material times, Franck's Pharmacy, Inc. (FPI), was a corporation organized and existing under the laws of Florida, conducting business as a retail pharmacy, and having its principal place of business in Ocala, Florida.

5. At all material times, Franck's Lab, Inc. (FLI), was a corporation organized and existing under the laws of Florida, conducting business as a compounding lab licensed as a pharmacy by the Florida Department of Health, and having its principal place of business in Ocala, Florida.

6. At all materials times, Anthony J. Campbell (Campbell) was a resident of Marion County, Florida, and employed by FLI or FPI as a pharmacist licensed and regulated by the Florida Department of Health.

7. At all material times, Quorum Management Corporation (Quorum) was a corporation organized and existing under the laws of Florida, and having its principal place of business in Wellington, Florida.

8. At all material times, Diamond State Insurance Company (Diamond) was a corporation organized and existing under the laws of Indiana, with its principal place of business in Hammond, Indiana.

9. At all material times, Diamond was engaged in the business of issuing insurance policies to indemnify against various, specified risks, including equine mortality, and authorized by the Florida Department of Financial Services to conduct business in Florida.

10. At all material times, Juan Martin Nero (Nero) was a citizen of Argentina who owned polo horses named Minibank, Princesa, Vasuda, Gausuncho, and Pelusa.

11. At all material times, Guillermo Caset (Caset) was a citizen of Argentina who owned polo horses named Holandesa and CanCan.

12. At all material times, Nicholas Espain (Espain) was a citizen of Argentina who owned polo horses named Monzone and Oracion.

13. At all material times, Quorum owned polo horses named Turca, Shakira, Platera, Cocota, Teletubi, Lunita, Xuxa, Frederica, Abrigadita, Julieta, Nina, and Mojarritta.

14. The amount in controversy exceeds the sum of $75,000.00, exclusive of interest, attorney's fees and costs, and this Court has diversity jurisdiction of this cause under 28 U.S.C. §1332.

15. Venue in the Middle District of Florida is proper, pursuant to 28 U.S.C. §1391(a), because more than one Defendant resides or has its principal place of business within the District and because one or more of the events giving rise to the claim occurred within the Ocala Division of the District, pursuant to Middle District Rule 1.02(b)(2)(c).

GENERAL ALLEGATIONS

16. On or about March 29, 2010, Defendants Quorum, Nero, Caset, Espain, and Diamond filed a Complaint for Damages and Demand for Jury Trial in the Circuit Court of Palm Beach County, Florida, Case No. 50 2010 CA 009112 XXXX MB ("the underlying action"). A copy of the Complaint is attached as Exhibit "A".

17. The Complaint in the underlying action was amended, and the claims presently asserted by Defendants Quorum, Nero, Caset, Espain, and Diamond are described by the Third Amended Complaint for Damages and Demand for Jury Trial, a copy of which is attached as Exhibit "B".

18. It is alleged in the underlying action that FPI and FLI (collectively referred to in the underlying action as "Franck's") were engaged in the "business of designing, formulating, compounding, manufacturing, selling, and distributing veterinary medications and nutritional supplements."

19. It is alleged further that on April 19, 2009, polo horses owned by Defendants Quorum, Nero, Caset, and Espain were killed by an injection of a nutritional supplement that was "designed, formulated, compounded, manufactured, sold and distributed" by FPI and FLI.

20. The nutritional supplement compound was allegedly ordered by a licensed veterinarian (James Belden, DVM) and then "re-formulized, compounded, and manufactured" by FLI and FPI.

21. The claims against FPI and FLI in the underlying action are for negligence and strict liability, based on the following alleged acts or omissions:

(a) compounding, re-formulating, or manufacturing, or all, a dangerously defective nutritional supplement compound that Franck's knew or reasonable should have known exposed Plaintiffs' polo horses to an unreasonable risk of harm;

(b) selling or distributing, or both, a dangerously defective nutritional supplement compound into the stream of commerce that Franck's knew or reasonably should have known subjected Plaintiffs' polo horses to an unreasonable risk of harm;

(c) failing to properly and adequately compound or manufacture, or both, the nutritional supplement compound before introducing it into the stream of commerce;

(d) failing to properly and adequately inspect or test, or both, the nutritional supplement compound before introducing it into the stream of commerce;

(e) improperly formulating, compounding, manufacturing, selling and distributing into the stream of commerce the nutritional supplement compound with dangerously high levels of sodium selenite in it that rendered the compound hazardous and unreasonably dangerous for its contemplated, forseeable and intended use;

(f) failing to provide adequate and sufficient warnings and instructions with respect to the nutritional supplement compound that rendered it defective and hazardous and unreasonably dangerous;

(g) failing to warn Plaintiffs and other intended users and consumers of the nutritional supplement compound of the aforesaid dangerously defective conditions that Franck's knew or reasonably should have known existed and created an unreasonable risk of harm to Plaintiff's polo horses;

(h) failing to correct the defective conditions that Franck's knew or reasonably should have known existed and created an unreasonable risk of harm to Plaintiffs' polo horses;

(i) failing to properly and adequately hire, train and supervise their agents, subagents, servants, representatives, workmen, employees and/or sub-contractors to ensure that proper and safe means and methods were used when designing, formulating, compounding, manufacturing, selling and distributing the nutritional supplement compound;

(j) failing to insure that proper and safe formulating and compounding practices were used when the nutritional supplement compound as manufactured, sold, and distributed into the stream of commerce;

(k) failing to apply the degree of skill that would customarily be brought to the formulating, compounding and manufacturing of the nutritional supplement compound by competent and skilled veterinary compounding pharmacies in and about the relevant community;

(l) failing to take proper and adequate precautions to protect Plaintiffs' polo horses from an unreasonable risk of harm;

(m) failing to perform their work in a good and workmanlike manner; and

(n) otherwise failing to use due care under the circumstances.

22. The claims of negligence and strict liability asserted against Campbell substantially mirror the claims against FPI and FLI.

23. Campbell was allegedly employed by "Franck's to participate in, oversee, manage, and supervise the formulation, compounding, manufacturing, and distribution of veterinary medications and nutritional supplements."

24. It is alleged also that "Franck's re-formulated, compounded, manufactured, sold, and distributed into the steam of commerce the nutritional supplement compound in a dangerously defective condition."

25. The allegedly negligent or defective compounding was completed before the supplement was sold, shipped, and administered to the polo horses owned by Defendants Quorum, Nero, Caset, and Espain.

26. FPI and FLI have been and continue to be defended in the underlying action by their professional liability insurer, and Campbell is likewise being defended under a professional liability insurance policy issued to him.

FLORIDA PHARMACY ACT

27. Florida law defines the "practice of the profession of pharmacy" to include "compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services." **Fla. Stat.** §465.003(13).

28. The practice of the profession of pharmacy also includes "any other act, service, operation, research, or transaction incidental to, or forming a part of, in any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession...." **Fla. Stat.** §465.003(13).

29. A "pharmacy" includes community, institutional, nuclear, special, and Internet pharmacies. **Fla. Stat.** §465.003(11)(a).

30. A "special pharmacy" includes "every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection." **Fla. Stat.** §465.003(11)(a)4.

31. Florida law defines "compounding" as the "professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent...." Fla. Admin. Code 64B16-27.700(1).

32. These statutory and administrative provisions were discussed in an unrelated matter arising out of the events described by the underlying action. In United States v. Franck's Lab, Inc., 816 F.Supp. 2d 1209 (M.D. Fla. 2011), the Court described the history and development of Franck's pharmacy business, and then summarized the incident that precipitated the underlying action as follows:

> The facts of his case are straightforward and largely undisputed. Mr. Franck, a Florida-licensed pharmacist in good standing since 1981, opened an independent pharmacy practice in Archer, Florida in 1983. Over the next several years, Franck expanded his practice by purchasing or opening additional retail pharmacies, including a location in Ocala in 1985. That same year, Franck began to compound medications at the Ocala location for humans and "non food-producing animals" (such as horses). The Ocala pharmacy was later expanded into two practices which now comprise Franck's: Franck's Lab, which operates as a compounding pharmacy, and Franck's Pharmacy, which is a traditional retail pharmacy. At the time the FDA instituted this action, Franck's employed

approximately 65 individuals full-time.

Animal and veterinary drug compounding comprises roughly 40 percent of Franck's Lab's business, while human drug compounding accounts for the remaining 60 percent. Franck's compounds the majority of its animal medications from "bulk" active ingredients, which it receives from suppliers outside the state of Florida. The company also receives prescription orders from customers outside Florida and ships its compounded products to those out-of-state customers. Franck's holds a valid pharmacy license in each of the 47 states in which it is required to do so, and nationwide, fills approximately 37,000 animal drug prescriptions per year.

In April, 2009, a veterinarian commissioned Franck's to compound an injectable solution of the prescription drug Biodyl for the Venezuelan national polo team. Due to a mathematical error in the conversion of an ingredient (which went unnoticed by the prescribing veterinarian), the compounded medication was too potent and 21 polo horses died. The incident was thoroughly invested by the Florida Board of Pharmacy, which imposed fines and reprimanded Franck's for the misfiled prescription. Despite the reprimand, the Board voted to allow Franck's to continue its pharmacy compounding practice without restriction, and Franck's remains in good standing in Florida.

816 F. Supp. 2d at 1211-13.

33. The same court discussed the process of "compounding":

Compounding is a process by which a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual human or animal patient. Compounding is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." Because the practice of pharmacy is state-governed, the States, including Florida, regulate compounding as part of their regulation of pharmacists.

Under Florida law, pharmacists may compound medications

> when they are prescribed for individual patients by a licensed medical practitioner (i.e., a veterinarian), or in anticipation of prescriptions based on routine, regularly observed prescribing patterns. This "triad" relationship among veterinarian, patient, and pharmacist envisions a compounding pharmacist working collaboratively with a veterinarian to provide a medication tailored to an animal patient's specific and individualized needs. The pharmacist-prescriber-patient relationship forms the basis of what is commonly known as "traditional pharmacy compounding."
>
> "Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." When a drug is not commercially available, or the commercially available drug is unsuitable for a particular patient, compounding is often the only way for a human or animal patient to obtain necessary medication for the safe and effective treatment of their condition. This is especially so for non food-producing animals because limited commercially available products exits and the available products are often in adequate due to the animal patient's size, species, and/or intolerance to active ingredients.
>
> Under Florida law, traditional compounding from bulk substances is an approved part of the practice of pharmacy. As a result, many, if not all, compounding pharmacies in Florida compound drug products from bulk ingredients. Florida is not an outlier in this regard; the practice of compounding from bulk ingredients is expressly recognized by many states and is a "widespread practice performed by the majority of licensed compounding pharmacy professionals throughout the country, and has been for decades. (citations omitted).

816 F. Supp. 2d at 1216-19.