

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

GLOBAL HEALTH)
INFORMATION/MEDICAL RESEARCH)
INSTITUTE, INC.,)
)
Petitioner,)
)
vs.) Case No. 03-2806F
)
DEPARTMENT OF HEALTH,)
)
Respondent.)
_____)

FINAL ORDER

Pursuant to notice, a formal hearing was held in this case in Tampa, Florida, on August 19, 2004, before Carolyn S. Holifield, a duly-designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Brandon L. Kolb, Esquire
Discovery Tours
Legal Department
35202 State Road 54
Zephyrhills, Florida 33541

For Respondent: Robert Daniti, Esquire
Department of Health
4052 Bald Cypress Way, BIN A02
Tallahassee, Florida 32399-1703

STATEMENT OF THE ISSUE

The issue is whether Petitioner is entitled to an award of attorney's fees and costs pursuant to Section 57.111, Florida

Statute (2003); and, if so, what is the amount of attorney's fees and costs that are recoverable by Petitioner.

PRELIMINARY STATEMENT

On July 28, 2003, Petitioner, Global Health Information Information/Medical Research, Inc. ("Global Health"), filed a Petition for Award of Attorney Fees and Costs ("Petition for Attorney's Fees") pursuant to Section 57.111, Florida Statutes (2003), and the Affidavit of James T. Kimball in Support of Global Health's Petition for Attorney Fees. The Petition for Attorney Fees requests attorney's fees and costs incurred by Global Health in litigating Department of Health v. Discovery Experimental, et al., Case No. 93-6184 (DOAH April 18, 2003), which consolidated four cases, DOAH Case Nos. 93-6184, 95-2255, 97-3836, and 98-4364. The Administrative Complaint filed by the Department of Health ("Department") in DOAH Case No. 97-3836 ("1997 Administrative Complaint" or "underlying proceeding") alleged that Global Health unlawfully promoted, advertised, and made medical claims for drug products which are not FDA approved, and are misbranded and adulterated. The undersigned issued a Recommended Order in the underlying proceeding on April 18, 2003.

The Recommended Order recommended that the Department dismiss the Administrative Complaint against Global Health. The Department's Final Order executed May 23, 2003, approved,

adopted, and incorporated by reference the Recommended Order in the underlying proceeding.

The Department denied that Global Health was the prevailing party in the underlying case and that Global Health is entitled to attorney's fees and costs. The Department asserted that it was substantially justified in filing the administrative action in the underlying proceeding.

By Amended Notice of Hearing issued September 3, 2003, the hearing in the matter was set for October 24, 2003. Prior to that date, the parties requested and were granted several continuances for good cause shown. Thereafter, the final hearing was rescheduled and held on August 19, 2004.

On March 10, 2004, this case was consolidated with Discovery Tour Wholesalers, Inc. v. Department of Health, DOAH Case No. 03-2754, and Josephine Kimball v. Department of Health, DOAH Case No. 03-2807, solely for the purpose of the final hearing because the three cases involved identical witnesses and documentary evidence. However, the parties and the undersigned agreed that a separate final order would be issued in each case.

Prior to the evidentiary part of the hearing, the undersigned denied the Department's Motion in Limine and/or the Department's Motion for Partial Judgment as to the maximum amount of attorney's fees that can be awarded to Petitioner, Discovery Tour Wholesaler, Inc., and Petitioner, Global Health.

At hearing, Petitioner presented the testimony of five witnesses: Josephine Kimball, Toni Kimball; Joy Young; Rolando Santiago, Esquire; and Jon Pellet, Esquire. The Department stipulated that Mr. Pellett was an expert witness with regard to this type of proceeding. Petitioner offered and had ten exhibits received into evidence. The Department presented the testimony of two witnesses: Jerry Hill, R.Ph., Bureau Chief of Statewide Pharmaceutical Services; and Deborah Orr, a former drug agent with the Department. The Department offered and had 12 exhibits received into evidence. The parties had five joint exhibits received into evidence.^{1/}

A Transcript of the proceeding was filed on September 3, 2004. At the conclusion of the hearing, the time for filing proposed final orders was set for ten days from the filing of the Transcript. Prior to that date, upon motion filed by the Department, the time for filing proposed final orders was extended until September 23, 2004. On September 22, 2004, the parties filed an agreed motion to extend the time for filing proposed final orders. The agreed motion was granted and extended the time for filing proposed final orders until October 8, 2004. Petitioner requested an additional extension, which was granted.

Both parties timely filed Proposed Recommended Orders under the extended time frames, which have been considered in preparation of this Final Order.

FINDINGS OF FACT

Based on the oral and documentary evidence presented at hearing and on the entire record of this proceeding, the following Findings of Fact are made.

1. The Department, through its Bureau of Statewide Pharmaceutical Services (formerly the Bureau of Pharmacy Services), is and was at all times relevant to this proceeding, the state agency responsible for administering and enforcing the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (1997), which includes the regulation of the manufacture, promotion, and distribution of prescription drugs.

2. In late 1990, the Department began investigating the unlawful advertising, manufacture, and distribution of prescription drugs that are not approved in commerce by the United States Department of Health and Human Services, Food and Drug Administration (FDA), of an establishment located at 29949 State Road 54 West, Wesley Chapel, Florida. The establishment was the primary business address of several closely held corporations owned and operated by James T. Kimball, and his wife, Josephine Kimball.

3. The Department initiated an Administrative Complaint in August 1993 (1993 Administrative Complaint), while in the middle of its investigation and after participating in a federal and state force of agencies that executed a search and seizure of the Kimballs' business establishment and their home located in Wesley Chapel, as well as other locations. The search and seizure took place on May 12, 1993, pursuant to federal warrants. The Kimballs' business establishment was located at 29949 State Road 54 West, in Wesley Chapel, Florida.

4. The 1993 Administrative Complaint was issued to Discovery Experimental & Development, Inc. ("DEDI"), and related to that company's alleged sale of drugs that were not approved by the FDA. DEDI was located at 29949 State Road 54 West, Wesley Chapel, Florida. After the 1993 Administrative Complaint was filed, the Department continued to investigate the activities of DEDI.

5. Deborah Orr (Agent Orr) began working for the Department as a drug agent in or about 1993 and was assigned to investigate the underlying case until the case culminated.

6. During the investigation, Agent Orr and others in the Department reviewed documents and other evidence seized during the search of the business establishment and the home of the Kimballs that tied both Mr. Kimball and Mrs. Kimball to several corporations that appeared to be connected to the manufacture

and sale of certain unapproved drugs. Among the documents seized, pursuant to the 1993 warrant, was Global Health's letterhead.

7. During the investigation and prior to 1997, Agent Orr visited the Global Health office. Global Health had one of the smaller offices, about 8x8 or 9x9, at "HQ," 15310 Amberly Drive, Suite 250, Tampa Palms in Tampa, Florida. In the Global Health offices were pamphlets put out by Global Health called "Silver Solutions" that promoted the colloidal silver products of DEDI, and later ASTAK, Inc. (ASTAK), and made medicinal claims despite the Department's previous warnings to Mr. Kimball and Mrs. Kimball that this was unlawful. It appeared that Global Health distributed these pamphlets.

8. Among the documents found and seized from the Kimballs' home, pursuant to the 1993 warrant and reviewed by Agent Orr, was the financial statement of "James and Josephine Kimball," dated April 14, 1992. According to that document, "James and Josephine Kimball" were 90-percent owners of DEDI, which "develops pharmaceuticals and chemicals for manufacturing" and had an assessed value of \$1,000,000; "James and Josephine Kimball" were 90-percent owners of ASTAK, a company that "manufactures custom order vitamins"; James Kimball was a 100-percent owner of Discovery Experimental and Development, Mexico N.A. (DEDI of Mexico), a company that "manufacture[s]

pharmaceuticals" and ships to 12 countries; and "James and Josephine Kimball" were 83-percent owners of Discovery Tour Wholesalers' Inc. (Tours), which owned the real property located at 29949 State Road 54 West, Wesley Chapel, Florida.

9. The Department's investigation indicated that several companies controlled by the Kimballs had separate and distinct functions related to the unlawful drug enterprise. For example, it appeared that one company manufactured the unlawful drugs, another took and filled orders from customers for the unlawful drugs, and another put out promotional information and literature about the unlawful drugs.

10. During the investigation, the Department determined that many of the companies controlled by Mr. and Mrs. Kimball and involved in unlawful drug distribution were located in the building owned by Tours and located at 29949 State Road 54 West, Wesley Chapel, Florida.

11. Prior to issuance of the 1997 Administrative Complaint in the underlying proceeding, Agent Orr wrote a report of her findings based on her multi-year investigation and sent them to her supervisor, who forwarded the report to Jerry Hill, R.Ph., Bureau Chief, Statewide Pharmaceutical Services of the Department. Mr. Hill reviewed the report that was prepared by Agent Orr and information and evidence obtained during the investigation. He also talked to some of the Department agents

and/or investigators who participated in the investigation at various times during the years the investigation was on-going.

12. Based on his review of Agent Orr's report and related information and evidence, Mr. Hill believed there were several companies involved in promoting and/or advertising, manufacturing, and distributing prescription drugs that were not approved by the FDA. The specific unapproved drugs were selegiline citrate (deprenyl) and some silvicidal products, some of which had been found during inspections of the premises at 29949 State Road 54 West, Wesley Chapel, Florida. Although Mr. Hill believed that some of the companies were more involved in the operation than others, he believed that all of the principals had some involvement in the illegal activity.

13. Based on the information Mr. Hill obtained prior to issuing the 1997 Administrative Complaint, he believed that Global Health had falsely advertised and made false claims about drugs containing silver that were manufactured by Respondents DEDI and ASTAK, non-prevailing parties in the underlying proceeding. In addition, Department drug agents had obtained samples of the unlawful silver drugs that appeared related to DEDI and ASTAK that made false claims on their labels, similar to the false and misleading advertisement of these drugs by Global Health. Mr. Hill believed that because of the common ownership of DEDI and ASTAK, the companies that he believed

manufactured, labeled, and sold the unlawful silver drugs, and Global Health, the apparent advertising arm of DEDI and ASTAK, the advertisements of Global Health constituted "labeling" and, thus, false or misleading advertisement of prescription drugs in violation of Chapter 499, Florida Statutes (1997), specifically Section 499.0054, Florida Statutes (1997).

14. Based on the information and evidence Mr. Hill had received, he believed that the corporations that were engaging in these activities involved two principal natural persons, Mr. and Mrs. Kimball.

15. Mr. Hill believed that he had sufficient evidence to tie DEDI, DEDI of Mexico, ASTAK, TOURS, and Global Health together. For example, the information Mr. Hill reviewed indicated that, except for Global, these entities were at the same address, 29949 State Road 54 West, in Wesley Chapel, Florida, and also had common ownership. Mr. Hill was concerned that if the Department did not tie the companies together and prosecute all the entities that were involved in the operation, the illegal activity would continue through some other company, and the unapproved drugs would get into commerce.

16. Mr. Hill believed that the situation described in paragraph 15 could happen based on another situation that occurred in or about 1991, when the Department initiated and settled an enforcement action against Discovery Distributing,

Inc. (Discovery Distributing), located at 29949 State Road 54 West, in Wesley Chapel, Florida, and its president, Mr. Kimball. The enforcement action related to Discovery Distributing's promotion of an unlawful product called Kimballac. Pursuant to the settlement in that aforementioned action, Mr. Kimball agreed not to manufacture or sell drugs that had not been approved by FDA. Yet, Mr. Hill learned that soon after the settlement was signed, the unlawful activities resumed with the same type of products being sold to the citizens of Florida.

17. After careful consideration of all the information and evidence provided to him by Department investigators, agents, and other Department officials familiar with and involved in the investigation, Mr. Hill concluded that Global Health had violated provisions of Chapter 499, Florida Statutes (1997), by making false and misleading advertisements about drugs that were not approved by FDA. Having made that determination on or about June 24, 1997, Mr. Hill issued the 1997 Administrative Complaint in the underlying proceeding, which was later assigned DOAH Case No. 97-3836.

18. Pursuant to a Delegation of Authority dated February 19, 1997, Mr. Hill was authorized to initiate and pursue to conclusion any legal or administrative action authorized by Chapter 499, Florida Statutes (1997).

19. In the underlying administrative proceeding, after taking and considering testimony and documentary evidence, the Administrative Law Judge issued a Recommended Order finding that the Department failed to establish by clear and convincing evidence that Global Health violated the provisions of Chapter 499, Florida Statutes (1997), as alleged by the Department. That Recommended Order was adopted in the Department's Final Order.

20. At all times relevant to this proceeding, Global Health was a Florida corporation with its primary office in Florida and had less than 25 employees and a net worth of less than \$2,000,000.

21. Global Health was represented by Elliot Dunn, Esquire, in the pre-hearing phase of the underlying proceeding and the first day of the 23-day final hearing. Mr. Dunn withdrew from the case after Mr. Kimball "fired" him during the proceeding.

22. Mr. Dunn, Esquire, did not testify at this proceeding and at no time records related to his representation of Global Health or any of the other Petitioners in the underlying proceeding were available for review, inspection, or consideration.

23. Global Health never paid Mr. Dunn for the legal services that he provided. Moreover, there was never a contract between Global Health and Mr. Dunn that defined the terms and

conditions of Mr. Dunn's legal representation on behalf of Global Health.

24. Petitioner's expert witness opined that a reasonable hourly rate for attorneys representing each of the Petitioners, including Global Health, was \$175 to \$350. The expert did not form an opinion as to the total number of hours reasonably spent by Mr. Dunn representing Global Health in the underlying proceeding. Rather, the expert testified that he utilized Rules Regulating Florida Bar 4-1.5, which deals with the reasonableness of fees and concluded that based on the factors in that rule, reasonable attorney's fees incurred by Global Health in the defense of the underlying case is \$12,000 to \$17,000, assuming the lower rate of \$175.

25. In light of the findings and conclusions reached in this Final Order, no findings are made or necessary regarding issues related to the reasonableness of the attorney's fees, the quality of the evidence presented on that issue, or any other issues related to attorney's fees.

CONCLUSIONS OF LAW

26. The Division of Administrative Hearings has jurisdiction over the subject matter and parties to this proceeding. §§ 57.111 and 120.57, Fla. Stat. (2004).

27. In proceedings to establish entitlement to an award of attorney's fees and costs pursuant to Section 57.111, Florida

Statutes (2003), the initial burden of proof is on the party requesting the award to establish by a preponderance of the evidence that it prevailed in the underlying action and that it was a small business party at the time the action was initiated.

28. Petitioner proved that it is a small business party within the meaning of Subsection 57.111(3)(d)1.b., Florida Statutes (2003). Furthermore, Petitioner established that the underlying action was initiated by the Agency. Therefore, Petitioner has met its burden of establishing that it is a prevailing small business party.

29. Because Petitioner met its burden, the burden shifts to the Department to demonstrate that its actions were substantially justified or that special circumstances exist, which would make an award of attorney's fees and costs unjust. Subsection 57.111(4)(a), Florida Statutes (2003), provides that unless the actions of the Respondent were substantially justified or there are special circumstances that would make an award unjust, an award of fees and costs shall be made to Petitioner.

30. In this case, the Department was substantially justified in initiating the underlying administrative action against Global Health. The evidence established that at the time the Department initiated the underlying administrative action against Global Health, the Department had a reasonable

basis in law and fact to believe that Global Health violated provisions of Chapter 499, Florida Statutes (1997).

31. The purpose of Section 57.111, Florida Statutes (2003), is to diminish the deterrent effect of defending against unreasonable government action because of the expense of civil actions and administrative proceedings. The Department satisfied its burden of showing that the governmental action against Global Health was not unreasonable at the time the Department initiated the action.

32. The fact that Respondent failed to prove the allegations in the Administrative Complaint by clear and convincing evidence does not raise a presumption that the Department was not substantially justified in initiating the administrative action against Global Health.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that Petitioner, Global Health Information/Medical Research Institute, Inc.'s, Petition for Attorney's Fees be DISMISSED.

DONE AND ORDERED this 3rd day of January, 2005, in
Tallahassee, Leon County, Florida.

Carolyn S. Holifield

CAROLYN S. HOLIFIELD
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 3rd day of January, 2005.

ENDNOTE

^{1/} The record in this case will be retained with the Final Order
in DOAH Case No. 03-2807F.

COPIES FURNISHED:

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original Notice of Appeal with the agency Clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.