

IN THE DISTRICT COURT OF APPEAL
FIRST DISTRICT, STATE OF FLORIDA

BIO-MED PLUS, INC.,
Petitioner,

NOT FINAL UNTIL TIME EXPIRES TO
FILE MOTION FOR REHEARING AND
DISPOSITION THEREOF IF FILED.

v.

CASE NO.: 1D05-1761

STATE OF FLORIDA,
DEPARTMENT OF HEALTH,

Respondent.

_____ /

Opinion filed October 20, 2005.

An appeal from an order of the Department of Health.

Sean M. Ellsworth of Ellsworth Law Firm, P.A., Miami Beach, for Petitioner.

Robert P. Daniti, Senior Attorney, Florida Department of Health, Tallahassee, for Respondent.

VAN NORTWICK, J.

Bio-Med Plus, Inc. (Bio-Med), a prescription drug distributor headquartered in Miami, Florida, petitions this court for review of an emergency suspension order (ESO) entered by the Department of Health (Department), respondent, pursuant to

which the Department has suspended Bio-Med's permit to distribute plasma-derivative pharmaceuticals.¹ Because the facts alleged in the ESO do not establish an immediate serious danger to the public health, safety or welfare, we grant the petition and quash the ESO.

I.

Bio-Med is a prescription drug distributor with distribution centers in six states and over 125 employees. Since 1996, it has possessed a state permit authorizing it to engage in the wholesale distribution of prescription drugs in or from Florida. Bio-Med is primarily engaged in the buying and selling of plasma-derivative prescription drugs that are used to treat viral diseases and immune and clotting deficiencies, including AIDS and hemophilia. Bio-Med asserts that it is the fourth largest distributor of plasma-derivative pharmaceuticals in the United States and the sole source supplier and distributor of plasma-derivative pharmaceuticals to the Veterans Administration hospitals in the United States.

On March 23, 2005, the United States Attorney in the Southern District of

¹This court has jurisdiction pursuant to section 120.68(1), Florida Statutes, and rule 9.100(a), Florida Rules of Appellate Procedure. See Commercial Consultants Corp. v. Dep't of Bus. Regulation, 363 So. 2d 1162, 1165 (Fla. 1st DCA 1978); Garcia v. Dep't of Prof'l Regulation, 581 So. 2d 960 (Fla. 3d DCA 1991). This court has previously granted Bio-Med's emergency motion for stay of the ESO pending final disposition of this proceeding.

Georgia filed an indictment against Bio-Med charging its principals and affiliates with, among other things, racketeering, racketeering conspiracy, mail and wire fraud, money laundering and conspiracy for various acts allegedly committed between November 1999 and January 2003. The indictment charges that the owners and officers of Bio-Med operated and controlled numerous entities through which they unlawfully obtained prescription drugs which were then fraudulently diverted to Bio-Med and sold in its wholesale distributions. It is also alleged that the affiliated entities, and certain other medical practitioners, fraudulently billed third-party providers for prescription drugs which were not actually dispensed or administered to patients but were diverted to Bio-Med.

Based solely upon the allegations contained within this indictment, the Department issued the ESO charging Bio-Med with several violations of the Florida Drug and Cosmetic Act, chapter 499, Florida Statutes. In the ESO, the Department specifically alleges, based on the allegations in the federal indictment, in pertinent part, as follows:

8. . . . Bio-Med Plus engaged in fraud, deceit, misrepresentation and subterfuge in the acquisition of prescription drugs for resale in violation of s. 499.005, (23), F.S.

9. . . . Bio-Med Plus acquired prescription drugs from persons not authorized under the Florida Drug and Cosmetic Act, Chapter 499, F.S., to distribute prescription

drugs to Bio-Med Plus. As a result, Bio-Med Plus acquired and resold or otherwise distributed prescription drugs that were adulterated, as defined in s. 499.006, F.S., in violation of s. 499.005(1) and (4), F.S., because the prescription drugs had left the regulatory controls established in federal and state law to protect the safety, integrity, and efficacy of prescription drugs.

10. . . . Bio-Med Plus failed to maintain records that truthfully reflect its acquisition of prescription drugs as required by ss. 499.001-499.081 and the rules adopted under those sections in violation of s. 499.005(18), F.S.

11. Based on the indictment, Bio-Med Plus is a danger to the public health, safety and welfare and has engaged in a persistent pattern of conduct demonstrating its unwillingness to abide by the Laws of the State of Florida that pertain to the regulation of the wholesale distribution of prescription drugs in that:

(a) Bio-Med Plus knowingly purchased or otherwise acquired and distributed over \$40 millions of dollars worth of adulterated prescription drugs on numerous occasions as set forth herein,

(b) Bio-Med Plus engaged in schemes to create documentation to conceal the actual source of the prescription drugs Bio-Med Plus acquired and resold or otherwise distributed, and

(c) The prescription drugs that Bio-Med Plus sold or otherwise distributed left the regulated channels for the lawful distribution of prescription drugs in this country and in Florida, thereby jeopardizing the integrity of these prescription drugs.

Bio-Med Plus therefore presents an unnecessary risk to the unsuspecting consuming public and their prescribing healthcare practitioners.

In the ESO, the Department concludes that:

Bio-Med Plus's continued operation as a prescription drug wholesaler during the pendency of the criminal case arising from the Indictment constitutes an immediate and serious danger to the health, safety and welfare of the public. Based on the allegations in the Indictment, Bio-Med Plus's pattern of conduct over a significant duration of time as a prescription drug wholesaler presents an unacceptable risk of injury to the frail and seriously ill consuming public and their prescribing practitioners.

II.

In our review, we must determine whether the ESO complies with the requirements of section 120.60(6), Florida Statutes (2004), and section 499.066(5), Florida Statutes (2004). See Field v. Dep't of Health, 902 So. 2d 893, 894-5 (Fla. 1st DCA 2005). Section 120.60(6) provides that, when the Department "finds that immediate serious danger to the public health, safety or welfare requires emergency suspension, restriction, or limitation of a license . . .," the Department

may take such action by any procedure that is fair under the circumstances if:

- (a) The procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the United States Constitution;

(b) The agency takes only that action necessary to protect the public interest under the emergency procedure; and

(c) The agency states in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances . . .

Similarly, section 499.066(5), Florida Statutes (2004), provides:

(5) The Department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

"Where, as here, no hearing was held prior to the entry of the emergency order, every element necessary to its validity must appear on the face of the order." Witmer v. Dep't of Bus. and Prof'l Regulation, 631 So. 2d 338, 341 (Fla. 4th DCA 1994) (citing Commercial Consultants Corp. v. Dep't of Bus. Regulation, 363 So. 2d 1162, 1164 (Fla. 1st DCA 1978)). It is not enough for the ESO merely to allege statutory violations. Robin Hood Group, Inc. v. Fla. Office of Ins. Regulation, 885 So. 2d 393, 396 (Fla. 4th DCA 2004). As we explained in Field:

Under section 120.60(6)(b) in an emergency action to suspend a license an agency may take only that action necessary to protect the public interest. In addition, an emergency order issued prior to a hearing must set forth facts sufficient to demonstrate immediate danger, necessity, and procedural fairness. Fairness requires that the order

provide a remedy that is tailored to address the harm and provide for an administrative hearing.

902 So. 2d at 895. (Citations omitted). Thus, to be sustained, the ESO must contain factual allegations which demonstrate that (i) the complained of conduct was likely to continue; (ii) the order was necessary to stop the emergency; and (iii) the order was sufficiently narrowly tailored to be fair. Bertany Assoc. for Travel and Leisure, Inc. v. Fla. Dep't of Fin. Servs., 877 So. 2d 854, 855 (Fla. 1st DCA 2004)(citing Premier Travel Int'l, Inc. v. State, Dep't of Agric. and Consumer Servs., 849 So. 2d 1132, 1134-37 (Fla. 1st DCA 2003)).

Section 499.067(1)(b)4, Florida Statutes (2004), provides that the Department may suspend a permit if any of the conditions enumerated in section 499.012(5) are present. In the ESO, the Department concluded that Bio-Med had violated section 499.012(5) in three respects: (1) Bio-Med's past experience in distributing prescription drugs poses a public health risk contrary to section 499.012(5)(f); (2) Bio-Med's affiliation through ownership and control with persons whose business operations are or have been detrimental to the public health is contrary to section 499.012(5)(g); and (3) Bio-Med and various affiliated parties have been charged with a felony in federal court and the disposition of those charges is pending contrary to section 499.012(5)(i).

III.

During the pendency of this ESO proceeding, the Department has filed an administrative complaint seeking to suspend permanently Bio-Med's permit on many of the same grounds it relies upon for the issuance of the ESO. This complaint provides Bio-Med the opportunity to challenge the Department's intended action by requesting an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes (2004). Establishing the basis for an emergency suspension without a hearing, however, places a greater burden on the Department than a proceeding under sections 120.569 and 120.57. As discussed above, to obtain an emergency suspension without hearing, under both section 120.60(6) and section 499.066(5), and applicable case law, among other things, the Department must set forth facts demonstrating an "immediate danger to the public health, safety or welfare" before an ESO may be entered.

The Department argues that, because Bio-Med and its affiliates have been charged with various felonies in the federal indictment, the requirements of sections 120.60(6) and 499.066(5) have been satisfied. Section 499.067(1)(b)4 permits the Department to suspend or revoke a permit if the Department finds that the "permittee . . . demonstrates any of the conditions enumerated in . . . s. 499.012(5)." Section 499.012(5) is a provision which authorizes the Department to "deny an application for a permit or refuse to review a permit for a prescription drug wholesaler" if the

applicant or permittee violates any of nineteen conditions listed in subsection (5). The condition set forth in paragraph (i) of subsection (5) permits a suspension if "[t]he applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period." Although proof of the violation of section 499.012(5)(i) may satisfy the Department's burden in a proceeding under sections 120.569 and 120.57, an issue we do not reach, an allegation of such a violation does not, by itself, satisfy the requirements of sections 120.60(6) and 499.066(5).

Although we do not question the seriousness of the allegations contained within the federal indictment or the Department's assertion that the drug industry warrants more intense regulation because it presents unique opportunities for immediate harm to the consuming public, U.S. v. Jamieson-McKames Pharmaceuticals, Inc., 651 F.2d 532 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982), the ESO does not contain a single, particularized allegation of a continuing public health or safety violation, or any allegations of harm or possible harm to any patient. The harm alleged in the Department's order is general and conclusory and relates to actions in excess of two years old. "General conclusory predictions of harm are not sufficient to support the issuance of an emergency suspension order." Daube v. Dep't of Health, 897 So. 2d 493, 495 (Fla. 1st DCA 2005). While the Department does allege that Bio-Med's

blood products have been "per se adulterated" because they were distributed by parties not authorized to do so under section 499.006(10),² the ESO contains no factual allegations that Bio-Med's plasma-derivative products were in any way counterfeited, altered, expired, or mislabeled; and no factual allegations to support a conclusion that the safety or welfare of the public is being threatened at present.³ Thus, neither immediate danger nor necessity for the ESO has been demonstrated.

This court has recognized that, if there are allegations of sufficiently egregious past harm which are of a nature likely to be repeated, a license may be suspended by emergency order, despite the lack of allegations establishing the "immediacy" of harm to the public. Bertany Assoc. for Travel and Leisure, Inc. v. Fla. Dep't of Fin. Servs., 877 So. 2d at 855. Here, however, unlike Bertany, there are no allegations in the ESO that the allegedly unlawful conduct charged in the indictment has continued or is

²Section 499.006(10), Florida Statutes (2004), provides that a drug is adulterated if it "has been purchased, held, sold or distributed at any time by a person not authorized under federal or state law to do so."

³Bio-Med alleges, without contradiction from the Department, that no state or federal agency has alleged any unlawful acts by Bio-Med, its principals or employees, since the last act in January 2003 alleged in the indictment; that the United States Attorney's Office has not sought to prevent Bio-Med from presently engaging in its regular business, despite the existence of the indictment; and that Bio-Med continues to supply a large volume of plasma-derivative pharmaceuticals to numerous hospitals operated by the U.S. Department of Defense and the U.S. Bureau of Prisons. Our review, however, is limited solely to the facts alleged in the ESO. See § 120.60(6)(c), Fla. Stat. (2004).

likely to be repeated. Further, the Department argues that, because the actions alleged in the indictment are so contrary to the public health and safety and continued over a long period of time, we should deem such actions as continuous and an immediate risk or danger to the public. Given the requirements of sections 120.60(6) and 499.066(5), we cannot agree. Nothing in the Department's ESO demonstrates that, because Bio-Med is alleged to have been involved in racketeering, conspiracy, and fraud offenses involving actions from 1999 to 2003, those offenses or any other actions in violation of chapter 499 are continuing or now present an immediate serious danger to the public health. See Crudele v. Nelson, 698 So. 2d 879, 880 (Fla. 1st DCA 1997)(reversing ESO which was based upon conduct that had occurred "well over two years before the issuance of the [ESO]" and there were "[n]o allegations or findings in the order . . . that would support an inference of such continuing conduct."). As we stated in Daube,

Punishment for past behavior is properly the subject of an administrative complaint pursuant to section 120.60(5) wherein the licensee is afforded the opportunity to challenge the factual basis of the complaint through a section 120.57(1) hearing.

897 So. 2d at 495.⁴

⁴Because of our holding, we are not required to address whether the Department's order was sufficiently tailored to be fair. See Premier Travel Int'l, Inc. v. Dep't of Agric. & Consumer Servs., 849 So. 2d 1132, 1137 (Fla. 1st DCA

PETITION GRANTED.

WEBSTER AND LEWIS, JJ., CONCUR.

2003).