[Cite as *Gentere, Inc. v. Ohio State Bd. of Pharmacy*, 2006-Ohio-4542.]

THE COURT OF APPEALS

ELEVENTH APPELLATE DISTRICT

LAKE COUNTY, OHIO

GENTERE, INC., d.b.a. TEREGEN LABS PHARMACEUTICALS, et al.,	:	**O P I N I O N**
Appellants,	:	**CASE NO. 2005-L-134**
- vs -	:	
OHIO STATE BOARD OF PHARMACY,	:	
Appellee.	:	

Administrative Appeal from the Court of Common Pleas, Case No. 04 CV 001297.

Judgment: Affirmed.

Joseph W. Diemert, Jr. and *Diane A. Calta*, 1360 S.O.M. Center Road, Cleveland, OH 44124 (For Appellants).

Jim Petro, Ohio Attorney General, and *Sally Ann Steuk*, Assistant Attorney General, 77 South High Street, Suite 1702, Columbus, OH 43215 (For Appellee).

WILLIAM M. O'NEILL, J.

{¶1} This is an accelerated calendar case. Appellants, Gentere, Inc., d.b.a. Teregen Labs Pharmaceuticals, ("Teregen Labs") and Christopher Kiel ("Kiel"), appeal the judgment entered by the Lake County Court of Common Pleas. In an administrative appeal, the trial court affirmed orders issued by appellee, the Ohio State Board of Pharmacy ("the Board").

{¶2} Teregen Labs operates a facility located in Willoughby, Ohio. Teregen Labs prepares drugs, which are sold to doctors' offices. The majority of the drugs Teregen Labs created were sterile, injectable drugs used to relieve joint pain. Beginning in 2000, Kiel was employed by Teregen Labs as a pharmacist.

{¶3} The central issue in this case concerns the distinction between "drug manufacturing" and "drug compounding." Simply stated, drug manufacturing is the production of drugs.[1] Pursuant to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), a new drug is not permitted to be introduced into the market without the approval of the Food and Drug Administration ("FDA").[2] Introduction of a new drug without FDA approval under the FDCA is a violation of Ohio law.[3]

{¶4} "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs."[4] Drug compounding is used when mass-produced medication does not suffice, such as when a patient is allergic to an ingredient in the mass-produced version.[5] The federal government has generally left the regulation of compounding to the states, and drug compounding has traditionally been exempt from approval under the FDCA. However, a concern has arisen that certain pharmacists have been "manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements."[6]

{¶5} For many years, Teregen Labs operated under a wholesale distributor

1. See, e.g., R.C. 3715.01(A)(14).
2. *Thompson v. W. States Med. Ctr.* (2002), 535 U.S. 357, 361.
3. R.C. 3715.65.
4. *Thompson v. W. States Med. Ctr.* (2002), 535 U.S. 357, syllabus.
5. Id. at 361.
6. Id. at 362.

license, issued by the Board pursuant to R.C. 4729.52. This license permitted Teregen Labs to engage in the wholesale sales of drugs, which are sales where the purchaser of the drug intends to resell the drug.[7] In contrast, a terminal distributor license permits the licensee to sell the drugs at a retail store.[8]

{¶6} In 1993, the Board issued a compliance bulletin, which stated that compounded prescriptions are prepared only for individual patients, pharmacists may not provide a supply of drugs to a practitioner for use in his or her office, and all prescriptions must bear the patient's name.

{¶7} In December 2000, Teregen Lags sought a terminal distributor license. It sent a letter to the Board indicating that it intended to comply with the Board's position "requiring an individual patient prescription for all compounded pharmaceuticals." The Board issued a terminal distributor license to Teregen Labs, pursuant to R.C. 4729.54. Kiel was listed as the responsible pharmacist for Teregen Labs, pursuant to R.C. 4729.27.

{¶8} Also in late 2000, Teregen Labs' counsel sent a letter to the FDA seeking an opinion as to whether individual patient prescriptions were required when sterile injectables are compounded for practitioners' office stock. The FDA responded with a letter indicating that the FDA's position was that compounding firms comply with state law. Further, the letter stated that the Director of the Board informed FDA officials that the Board would process Teregen Labs' license application "after Teregen's promise not to compound drug products, except under individual patient prescriptions, until such

7. R.C. 4729.01(K) and (O).
8. R.C. 4729.01(Q). See, also, 1980 Ohio Atty.Gen.Ops. No. 80-001, paragraph one of the syllabus.

time as FDA confirmed the matter of compounding of 'physicians' office stock' in writing."

{¶9} Upon receipt of this letter, counsel for Teregen Labs sent a letter to George Fiderio of Teregen Labs, indicating counsel's position that compounding for physician office stock may be permissible under Ohio Law. Counsel cited R.C. 3715.01(A)(14)(b)(ii), which provides that compounding for a physician, who administers the drugs at his or her office, is not "manufacturing."

{¶10} In light of counsel's letter, Teregen Labs began producing drugs for physician office stock. Teregen Labs engaged in a high-scale production of various injectable drugs, shipping thousands of doses to medical offices in 45 states.

{¶11} In August 2003, the Board conducted a routine inspection of Teregen Labs' facility. The Board notified Teregen Labs that it believed the lab to be in violation of various statutes for illegally compounding drugs. The entities exchanged communications during the fall of 2003. Finally, the Board sent notices for opportunity for hearing to Kiel and Teregen Labs, alleging they violated R.C. 4729.01 and 3715.65.

{¶12} In March 2004, the Board conducted a second inspection of Teregen Labs' premises. The inspection revealed that Teregen Labs was continuing to compound drugs for physician office stock, without individual patient prescriptions. In fact, the Board noted that Teregen Labs produced 17,599 multidose vials of injectable drugs in the 128 days prior to the March 2004 inspection.

{¶13} A hearing was held before the Board in May 2004. At the hearing, Joanne Predina, a compliance officer for the Board, and Frederick Lochner, an investigator with

the FDA, testified for the Board. These were the individuals who conducted the inspections of Teregen Labs' facilities. Kiel testified for appellants.

{¶14} Following the hearing, the Board found appellants to be in violation of R.C. 3715.65 and Ohio Adm.Code 4729-9-21. Specifically, in regard to Teregen Labs' wholesale distributor license, the Board found 33 violations of R.C. 3715.65. In regard to Teregen Labs' terminal distributor license, the Board found 33 violations of R.C. 3715.65 and 33 violations of Adm.Code 4729-9-21. Further, the Board found three violations of Ohio Adm.Code 4729-5-30(F) and two violations of R.C. 4729.51(C). Similarly, as to Kiel, the Board found 33 violations of R.C. 3715.65, 33 violations of Adm.Code 4729-9-21, three violations of Ohio Adm.Code 4729-5-30(F), and two violations of R.C. 4729.51(C).

{¶15} The Board imposed several sanctions on Teregen Labs and Kiel. In regard to Teregen Labs' wholesale distributor license, the Board ordered Teregen Labs to cease distributing drugs that have not been approved by the FDA. Further, the Board imposed a $6,000 fine against Teregen Labs in relation to this license. The Board revoked Teregen Labs' terminal distributor license and imposed a $25,000 fine against Teregen Labs regarding this license. The Board fined Kiel $10,000 and suspended his license for six months. In addition, he was placed on probation for two years.

{¶16} Appellants appealed the orders of the Board to the trial court pursuant to R.C. 119. The trial court heard oral arguments on the matter. Thereafter, the trial court found the Board's orders were supported by the preponderance of substantial, reliable, and probative evidence. Thus, the trial court upheld the Board's decision. Appellants have timely appealed the trial court's decision to this court.

{¶17} Appellants raise three assignments of error. Their first and second assignments of error are:

{¶18} "[1.] The ruling of the court of common pleas was in error because it was not in accordance with the law and should be reversed.

{¶19} "[2.] The court of common pleas erred by finding reasonable the policy of the Ohio State Board of Pharmacy that prohibits the compounding of drugs for physicians' office stock."

{¶20} Due to the related nature of these assigned errors, they will be addressed in a consolidated fashion.

{¶21} The standard of review for administrative appeals is set forth in R.C. 2506.04, which provides:

{¶22} "[T]he court may find that the order, adjudication, or decision is unconstitutional, illegal, arbitrary, capricious, unreasonable, or unsupported by the preponderance of substantial, reliable, and probative evidence on the whole record. Consistent with its findings, the court may affirm, reverse, vacate, or modify the order, adjudication, or decision, or remand the cause to the officer or body appealed from with instructions to enter an order, adjudication, or decision consistent with the findings or opinion of the court. The judgment of the court may be appealed by any party on questions of law as provided in the Rules of Appellate Procedure and, to the extent not in conflict with those rules, Chapter 2505. of the Revised Code."

{¶23} When determining whether the administrative order is unsupported by the preponderance of substantial, reliable, and probative evidence, the "common pleas court considers the 'whole record,' including any new or additional evidence admitted

under R.C. 2506.03[.]"[9] However, our standard of review is not as broad. As stated by the Supreme Court of Ohio, "'[R.C. 2506.04] grants a more limited power to the court of appeals to review the judgment of the common pleas court only on "questions of law," which does not include the same extensive power to weigh "the preponderance of substantial, reliable and probative evidence," as is granted to the common pleas court.'"[10]

{¶24} The Board charged appellants with violations of R.C. 3715.65, which provides:

{¶25} "(A) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the 'Federal Food, Drug, and Cosmetic Act,' 52 Stat. 1040, 21 U.S.C.A. 301, as amended."

{¶26} Further, the Board found Kiel and Teregen Labs, in regard to its terminal distributor license, in violation of Ohio Adm.Code 4729-9-21, which provides, in part:

{¶27} "(F) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns."

{¶28} Appellants concede that they did not have FDA approval to distribute the drugs at issue. The Board found that Teregen Labs, under its wholesale distributor license, violated R.C. 3715.65 11 individual times during each of the years 2001, 2002,

9. *Henley v. Youngstown Bd. of Zoning Appeals* (2000), 90 Ohio St.3d 142, 147, citing *Smith v. Granville Twp. Bd. of Trustees* (1998), 81 Ohio St.3d 608, 612.
10. *Henley v. Youngstown Bd. of Zoning Appeals*, 90 Ohio St.3d at 147, quoting *Kisil v. Sandusky* (1984), 12 Ohio St.3d 30, 34, at fn. 4.

and 2003. In any one year, each of the violations pertained to a different drug. Similarly, in regard to Teregen Labs' terminal distributor license, the Board found 11 violations of R.C. 3715.65, per year, from 2001 through 2003. Also, in regard to the terminal distributor license, the Board found 11 violations of Ohio Adm.Code 4729-9-21. Finally, Kiel was found to have individually violated R.C. 3715.65 and Ohio Adm.Code 4729-9-21 the same number of times as there were violations charged to Teregen Labs' terminal distributor license.

{¶29} The evidence elicited indicated that Teregen Labs was producing thousands of multidose vials per month. Further, only one of the drug orders was filled pursuant to a patient-specific prescription. Kiel was the responsible pharmacist for Teregen Labs during the times of the violations.

{¶30} Appellants do not dispute the quantity of drugs produced during the timeframe, rather they argue, as they did before the Board and at the trial court level, that their operations qualify as compounding. Compounding would not be subject to R.C. 3715.65.

{¶31} At the time of the infractions in the instant matter, compounding was defined in R.C. 4729.01(C), which provided:

{¶32} "'Compounding' means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

{¶33} "(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

{¶34} "(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;

{¶35} "(3) As an incident to research, teaching activities, or chemical analysis;

{¶36} "(4) In anticipation of prescription drug orders based on routine, regularly observed dispensing patterns."[11]

{¶37} We note this statute was amended effective August 19, 2005. The amended version of the statute provides that compounding for office stock may be permissible in certain circumstances. The amended statute does place restrictions on the practice, including that only a "limited quantity" of the drug is compounded and that compounding for office stock is an "occasional exception" to the regular practice of compounding only for "patient-specific prescriptions."[12] Since this statute was amended following the violations at issue and appellants do not contend it is controlling, we will continue our analysis pursuant to the version of the statute in effect at the time the incidents occurred.

{¶38} Appellants argue that their practices were exempted due to the following provision:

{¶39} "'Manufacture' does not include the preparation, compounding, packaging, or labeling of a drug by a pharmacist as an incident to either of the following:

{¶40} " ***

{¶41} "Providing a licensed health professional authorized to prescribe drugs with a drug for the purpose of administering to patients or for using the drug in treating patients in the professional's office."[13]

{¶42} Appellants assert that, pursuant to R.C. 3715.01(A)(14)(b)(ii), they were

11. R.C. 4729.01(C).
12. R.C. 4729.01(C)(5)(b) and (c).
13. R.C. 3715.01(A)(14)(b)(ii).

"compounding" the drugs and providing them to licensed health professionals. The problem with appellants' argument is that their practices were not consistent with "compounding" as it was defined in R.C. 4729.01(C). The evidence demonstrated appellants were producing thousands of multidose vials per month, and these vials were being shipped to medical offices around the country. Moreover, except for a single, isolated instance, none of the orders were provided pursuant to a patient-specific prescription. Since appellants were not "compounding," they could not take advantage of the exception delineated in R.C. 3715.01(A)(14)(b)(ii).

{¶43} Appellants advance a public policy argument, i.e., that compounding should be defined to include preparing drugs for physicians' office stock. However, we decline to engage in this analysis, as we must interpret the statutes and administrative code sections as written.

{¶44} Upon review of the record, we conclude that the trial court correctly determined that the Board's orders were supported by the preponderance of reliable, probative, and substantial evidence.

{¶45} Appellants' first and second assignments of error are without merit.

{¶46} Appellants' third assignment of error is:

{¶47} "The court of common pleas erred by finding that the fines and additional penalties imposed by the order of the Ohio State Board of Pharmacy were not excessive and unreasonable."

{¶48} If an administrative sanction is supported by substantial, reliable, and probative evidence, it should not be overturned on appeal.[14] Further, courts should not

14. (Citation omitted.) *CVS/Pharmacy #3131 v. Ohio State Bd. of Pharmacy*, 8th Dist. No. 82215, 2003-Ohio-3806, at ¶30.

modify a penalty that is within the scope of the authority granted to the imposing agency.[15]

{¶49} Appellants argue that the Board was permitted to take action against their licenses *or* fine them, but not both. The Tenth Appellate District has addressed the Board's ability to impose monetary fines in addition to revoking a license under R.C. 4729.56 and 4729.57.[16] The court held "[a]lthough the board may not impose both penalties for any *one* violation of R.C. 4729.56(A) through (D) or 4729.57(A)(1) through (7), the board is empowered to impose both penalties where each penalty is based on different violations of the statutes."[17]

{¶50} As the trial court noted, there were at least 33 individual violations committed by Kiel and Teregen Labs, with respect to its licenses. Thus, the Board could have imposed the sanction against the licenses as a result of the initial violations. The Board could then have imposed monetary penalties for the subsequent violations.

{¶51} Appellants contend that the amount of the sanctions should have been limited to $1,000 for each of Teregen Labs' licenses and $500 against Kiel.

{¶52} "[The Board] may suspend, revoke or refuse to renew any [license] or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or one thousand dollars [five hundred dollars for purposes of R.C. 4729.16] if the acts committed are not classified as an offense by the Revised Code[.]"[18]

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15. Id. at ¶31.
16. *Wesco Ohio Limited v. Ohio State Bd. of Pharmacy* (1988), 55 Ohio App.3d 94, 98.
17. (Emphasis in original.) Id., citing *Distributors Pharmacy, Inc. v. Ohio State Bd. of Pharmacy* (1987), 41 Ohio App.3d 116, 117-118.
18. R.C. 4729.56(A) and R.C. 4729.57(A). See, also, R.C. 4729.16(A).

{¶53} Appellants are focusing on the maximum penalties that may be imposed for a single violation. There is nothing in these statutory sections that prohibits the Board from "stacking" the penalties imposed for multiple violations. Moreover, the *Wesco* decision suggests that stacking is appropriate.[19] The trial court observed that a violation of R.C. 3715.65 also constitutes a violation of R.C. 2925.09(A), which is a fourth or fifth degree felony and carries a maximum penalty of $2,500 or $5,000. As previously noted, there were 33 violations against each of Teregen Labs' licenses, as well as Kiel. Therefore, the fines imposed by the Board were well within the scope of its authority.

{¶54} Appellants argue that the Board should not have imposed fines in relation to Teregen Labs' wholesale distributor license, because, they assert, all of the production of drugs occurred under Teregen Labs' terminal distributor license. However, the Board found Teregen Labs committed violations under its wholesale distributor license. Thus, the Board was permitted to impose sanctions in regard to this license.

{¶55} We note that the violations attributed to Kiel and Teregen Labs' terminal distributor license involved identical conduct. However, the Tenth Appellate District has held "[w]here the same conduct constitutes a violation by both a pharmacist and the holder of a terminal distributor's license, both penalties may be imposed."[20]

{¶56} The trial court did not err by upholding the sanctions imposed by the Board.

19. *Wesco Ohio Limited v. Ohio State Bd. of Pharmacy*, 55 Ohio App.3d at 98.
20. Ohio *State Bd. of Pharmacy v. Dick's Pharmacy*, 150 Ohio App.3d 343, 2002-Ohio-6500, at ¶32.

{¶57} Appellants' third assignment of error is without merit.

{¶58} The judgment of the trial court is affirmed.

DONALD R. FORD, P.J.,

CYNTHIA WESTCOTT RICE, J.,

concur.