IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

NEW MEXICO BOARD OF PHARMACY
and NEW MEXICO MEDICAL BOARD,
Appellants,
v.
NEW MEXICO BOARD OF
CHIROPRACTIC EXAMINERS,
Appellee,

and

INTERNATIONAL CHIROPRACTORS ASSOCIATION,
Appellant,
v.
NEW MEXICO BOARD OF
CHIROPRACTIC EXAMINERS,
Appellee.

No. 31,668
No. 31,690
[CONSOLIDATED under Ct. App. 31,690]

Oral Argument Requested

Direct Appeal from Rulemaking by
Appellee New Mexico Board of Chiropractic Examiners

REPLY BRIEF OF APPELLANT, INTERNATIONAL CHIROPRACTORS ASSOCIATION

Charles V. García
Cuddy & McCarthy LLP
7770 Jefferson Street NE, Ste. 305
Albuquerque, NM 87109
(505) 888-1335; FAX (505) 888-1369
Attorney for Appellant

James S. Turner
Swankin & Turner
1400 16th Street, NW, Suite 101
Washington, D.C. 20036
(202) 462-8800; FAX (202) 265-6564
Of Counsel

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I. The Court Should Interpret the Statute to Meet the Intent and Purpose of Legislative Policy to Protect Public Health and Welfare.

In interpreting the Chiropractic Physicians Practice Act, the court must consider the interlinking provisions of the Pharmacy Act, the Medical Practice Act, and the Drug, Device and Cosmetic Act, given their legislative purpose, i.e., to protect public health and well-being by ensuring that those who provide services and administer drugs to the public pursuant to these statutes do so in compliance with the licensing requirements and standards covering the specific treatment and drugs established by statutory mandate and properly enacted administrative rules. New Mexico law is well established that the court should examine the overall structure of the statute and its function in the comprehensive legislative scheme. *State v. Smith*, 136 N.M. 372, 98 P.3d 1022, 2004 NMSC 32 (N.M., 2004). In addition to the plain language of the statute, its history and background and how the specific statute fits within the broader statutory scheme must be considered, including an assessment of how its construction implicates public policy. *Chatterjee v. King,* 1012-NMSC-019 , ¶ 12, 280 P.2d 383, 287 (2012). And, when construing statutes related to the same subject matter, the provisions of those statutes must be read together so that they may be harmonized and construed together, when possible, in a way that facilitates their operation and the achievement of their goals. *Attorney General v. N.M. Pub. Regulation Comm'n,*

2011-NMSC-034, ¶ 10. Indeed, it is error to interpret one section of a statute literally in isolation from other provisions of the statute; and the court must look at the overall structure of the statute and its function within the comprehensive legislative scheme. *TNT Taxi, Ltd. v. N.M. Pub. Regulation Comm'n,* 2006-NMSC-016, 139 N.M. 550, 135 P.3d 814. Here, the Chiropractic Board is charged with establishing mandatory continuing education requirements for chiropractic physicians and certified advanced practice chiropractic physicians ("APCP") "for the purpose of protecting the health and well-being of the citizens of this state and maintaining and continuing informed professional knowledge and awareness." NMSA § 61-4-3(G). Therefore, the legislative framework of protecting public health and well-being provides further evidence that the legislature intended to implement several layers of protection – i.e., Pharmacy and Medical Board approvals – before new and potentially harmful items may be administered to patients. This legislative framework has resulted in statutory provisions that ensure those pharmacological and medical boards established under New Mexico law have direct review and approval authority over the formulary adopted by the Chiropractic Board, and is clearly reflected in the Chiropractic Board's own rules for making changes to the formulary. *See* § 16.4.15.8.H NMAC.

The statutory and regulatory framework in New Mexico is one that provides checks and balances among the three boards to ensure that the authorized

chiropractic treatment will ultimately prove beneficial and serve the public interest. Contrary to arguments presented in Appellee's brief, which frames the issue in terms of the allocation of power among the three boards and makes the statement that Appellants' arguments "really limits the power of an Advanced Practice Chiropractor's prescriptive authority regarding the formulary" (Br. at 9), the overriding issue before the court is the public health and safety of patients who receive treatment from APCPs. This takes on heightened significance in light of the fact that the New Mexico legislature is among the first in the nation to grant prescription drug rights to licensed chiropractors. Given the historical clear lines of distinction between the practice of medicine and the practice of chiropractic, and that the practice of chiropractic has traditionally been a drugless and non-surgical approach, it is fundamentally sound public policy for the New Mexico Legislature to grant the prescription drug rights to APCPs under the supervision and upon review and approval of both the Pharmacy and Medical Boards. This check on the ability of APCPs to prescribe and administer drugs is further borne out by the Legislature's specific definitional limitation that the practice of chiropractic "shall exclude operative surgery, the prescription or use of controlled or dangerous drugs," among other things. §61-4-2(C). For this very reason, the Legislature established the statutory and regulatory framework that requires Medical and Pharmacy Board approvals for the prescription and administration of certain drugs

by APCPs, and specifically requires Medical Board approval of institutions that provide the training and certification of APCPs in New Mexico.

The science and practice of chiropractic has, from its very conception, been a drugless approach to health care. This self-definition as a drug-free healing methodology has been recognized and codified in every state, and historically served to distinguish the practice of chiropractic from the practice of medicine and other healing arts and professions. Chiropractic is defined in most states as an exception to medical practice and by definition excludes the practice of medicine. The authorization provided by the New Mexico legislature to APCPs to prescribe and administer certain drugs represents a major paradigm shift for the chiropractic profession in New Mexico. Furthermore, the educational standards of the Council on Chiropractic Education do not include education on injection techniques or the proper use of prescription drugs, and the testing of the National Board of Chiropractic Examiners does not include testing for the credentialing of the practice of medicine. For these reasons, the Legislature mandated the checks and balances of the Pharmacy and Medical Boards. This issue presented to this Court cannot be viewed as a "turf war" between the Chiropractic, Pharmacy, and Medical Boards, where the Chiropractic Board argues it is a "co-equal" board and should not be viewed as being "subservient" to the other two. Rather, the overarching issue before the Court is the public health and safety of patients in New Mexico

who seek and receive chiropractic treatment.

II. The Court Must Apply the Plain Meaning Rule With Caution Given the Broader Statutory Scheme that Mandates Review and Approval by the Pharmacy and Medical Boards.

The classic canons of statutory construction require looking first to the plain language of the statute, giving the words their ordinary meaning unless the legislature indicates a different one was intended. As noted above, however, the plain language of the statute must be considered in the context of the broader statutory scheme and the function of the specific statute at issue within that comprehensive legislative scheme. Although legislative intent is first sought by reference to the statute's plain meaning, New Mexico courts have rejected formalistic and mechanistic interpretation of statutory language. *D'Avignon v. Graham*, 113 N.M. 129, 131, 823 P. 2d 929, 931 (Ct. App. 1991). This principle in applying the plain language rule has long been established in New Mexico. "Not only must the legislative intent be given effect, but the court will not be bound by a literal interpretation of the words if such strict interpretation would defeat the intended object of the legislature." *State v. Nance*, 77 N.M. 39, 46, 419 P.2d 242, 247(1966), *cert denied*, 386 U.S. 1039 (1967).

While the plain meaning rule is clearly the place for the court to start its statutory interpretation analysis, it is not the only consideration, and indeed, courts must exercise caution in applying the plain meaning rule: "Its beguiling simplicity

may masks a host of reasons why a statute, apparently clear and unambiguous in its face, may for one reason or another give rise to legitimate (i.e., nonfrivolous) differences of opinion concerning the statute's meaning." *State el rel. Helman v. Gallegos*, 117 N.M. 346, 353, 871 P.2d 1352, 1359 (1994). In such case, "it is the high duty and responsibility of the judicial branch of government to facilitate and promote the legislature's accomplishment of its purpose." *Id.* Clearly, the legislative purpose in enacting the provisions of the Chiropractic Physicians Practice Act as written was to grant APCPs the ability to prescribe and inject certain substances and drugs into their patients after review and approval by the Pharmacy and Medical Boards. Under plain meaning interpretation of § 61-4-9.2(B) as argued by Appellee, the Chiropractic Board would have unfettered autonomy to develop and approve a formulary that allows APCPs to prescribe and inject all substances listed in Subsection A, even when the manner of use or the injection of such substances make them "dangerous drugs" under other New Mexico statutes developed and designed to protect the public health and well-being, e.g., the Drug, Device and Cosmetic Act, NMSA 1978 § 26-1-2.E *et seq.* Such an interpretation creates clear risks to the health and welfare of patients in this unchartered territory of chiropractic practitioners exercising the power to prescribe and inject substances into their patients without review and approvals of the Pharmacy and Medical Boards. Without a doubt, the legislative purpose was to

ensure both the Pharmacy and Medical Boards had a significant role in the substances and drugs to be prescribed and administered by APCPs, and certainly was not to authorize the Chiropractic Board to act autonomously.

III. Substances Administered by Injection Become "Dangerous Drugs."

Appellant ICA maintains that a substance listed in § 61-4-9.2(A) that is to be administered by injection becomes a "dangerous drug" under § 26-1-2(F) of the New Mexico Drug, Device and Cosmetic Act, NMSA 1978. § 26-1-2(F) defines "dangerous drug" as:

> "a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or *the method of its use* or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug..."

(emphasis added). The Pharmacy Board's rule 16.19.17.7(B)(2) NMAC provides:

> "A dangerous drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe such drug."

Both the above statutory definition of "dangerous drug" and the Pharmacy Board's rule regarding "dangerous drugs" were in place before the challenged formulary was adopted. The legislature is presumed to have acted with full knowledge of existing laws. *Attorney General v. N.M. Pub. Regulation Comm'n,* 2011-NMSC-034 at ¶ 10. Therefore, at the time of enacting § 61-4-9.2(B), the legislature is presumed to have known that under § 26-1-2(F), substances listed in § 61-4-9.2(A) that are to be injected will fall under the definition of "dangerous

drugs" because of the "potentiality for harmful effect," and also because "the method of their use ... is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug." Since these substances listed in Subsection A become "dangerous drugs" when injected, Pharmacy Board and Medical Board approval is required under Subsection B.

IV. Substances Listed in Subsection A May Be "Drugs."

Appellant ICA also maintains that a substance listed in Subsection A becomes a "drug" when "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease," or used to "affect the structure or any function" of the body, or "intended for use as a component of [a drug]." NMSA § 26-1-2(E). Appellant does not argue that substances listed in Subsection A are necessarily "drugs." However, if the method of their administration creates a potentially harmful effect, and specifically if the substance is to be administered by injection, the substance does become a "drug" and must be approved by the Pharmacy and Medical Boards under Subsection B.

V. Plain Statutory Language Shows that the Phrase, "Not Listed in Subsection A," Only Modifies the Term, "Substances."

Directly in contravention of rules of statutory construction, Appellee argues that the phrase, "not listed in Subsection A," modifies all three items listed in § 61-4-9.2(B) as such:

1. dangerous drugs or controlled substances;

2. drugs for administration by injection; and

3. substances. (Br. at 14.)

The "last antecedent rule" provides that "relative and qualifying words, phrases, and clauses are to be applied to the words or phrase immediately preceding, and are not to be construed as extending to or including others more remote." *State v. Johnson*, 15 P.3d 1233, 1242, 130 N.M. 6, 2001 NMSC 1 (N.M., 2000) (dissent, J. Minzer) (*citing Hale v. Basin Motor Co.*, 795 P.2d 1006, 1010 (1990) (internal citation omitted)). Applying the last antecedent rule, the court has held that under a statute requiring an automobile seller to disclose whether there has been an "alteration or chassis repair due to wreck damage," the phrase "due to wreck damage" only modifies the immediately preceding phrase "chassis work." *Hale v. Basin Motor Co.*, 795 P.2d at 1009.

Therefore, the rules of statutory construction dictate that the phrase, "not listed in Subsection A," only modifies the term immediately preceding it – namely, the term, "substances." The principal command of statutory construction is that the plain language of the statute is the primary indicator of legislative intent. *State v. Ogden*, 118 N.M. 234, 242, 880 P.2d 845, 853 (1994). Here, contrary to Appellee's argument, the plain language of the statute indicates that the legislature intended the following to each be a separate term:

1. "[d]angerous drugs or controlled substances";

2. "drugs for administration by injection"; and

3. "substances not listed in Subsection A."

VI. Legislative History Shows Intent to Require Medical and Pharmacy Board Approvals for Dangerous Drugs, Controlled Substances, Drugs to Be Administered by Injection, and Substances Not Listed in Subsection A

Contrary to Appellee's argument (Br. at 5-7), legislative history shows that the 2009 legislature indeed intended Pharmacy Board and Medical Board approvals for injection of substances listed in 61-4-9.2 (A). 61-4-9.2 (B) was enacted as follows, with the strikethrough indicating portions that were struck from, and the underlined text indicating portions added to, the proposed draft:

> "A formulary that includes all substances listed in Subsection A of this section, including compounded preparations for topical and oral administration, shall be developed and approved by the board. ~~***A certified advanced practice chiropractic physician may administer by non-epidural and non-intrathecal injection vitamins and minerals, amino acids, homeopathic remedies, dextrose, Ringers solution, sterile water, sterile saline, sodium bicarbonate, Sarapin or its generic, caffeine and procaine HCL epinephrine SQ.***~~ A formulary for injection that includes ~~these substances for injection and drugs or controlled substances~~ the substances in Subsection A of this section that are within the scope of practice of the certified advanced practice chiropractic physician shall be developed and approved by the board. ~~Drugs~~ Dangerous drugs or controlled substances, ~~and~~ drugs for administration by injection and substances not listed in Subsection A of this section shall be submitted to the board of pharmacy and the New Mexico medical board for approval."

61-4-9.2 (B), 2009 N.M. Session Laws, Ch. 260 (emphasis added in bold italic.)

The second sentence (in bold italic), which was stricken, lists various substances, some of which are already listed in Subsection A – e.g., vitamins,

minerals, and amino acids. This sentence would have authorized APCPs to administer the substances listed in that sentence by injection, without Medical Board and Pharmacy Board approvals. Therefore, the striking of this sentence shows that the legislature did not intend to authorize such. Importantly, by extension, this shows that the legislature did not intend to authorize APCPs to administer by injection, without Pharmacy and Medical Board approvals, all of the substances listed in Subsection A – for example, all vitamins, all minerals, etc.

Notably, in the last sentence of the version enacted into law, a comma was inserted after "controlled substances" and the word, "and," was deleted before "drugs for administration by injection." This indicates legislative intent to treat the following as separate categories, and that the phrase, "not listed in Subsection A," does not modify all three preceding categories:

1. "[d]angerous drugs or controlled substances";
2. "drugs for administration by injection"; and
3. "substances not listed in Subsection A."

Appellee argues that Dr. Perlstein's and Dr. Jones's testimonies at the rule hearing provide evidence that the supporters of the new law intended for the items in Subsection A, regardless of the method of administration, to be under the exclusive purview of the Chiropractic Board (Br. at 12-13). However, Ms. Lynn Hart, Executive Director of the Medical Board, who also attended the task force

meeting attended by Drs. Perlstein and Jones, testified that "it was very clear the legislature wanted the medical Board to be involved with anything involving dangerous drugs, anything prescribed, and controlled substances and injectables." CHIRO 262.

VII. Section 16.4.15.12 NMAC Contravenes Statutory Requirements and the Chiropractic Board's Own Administrative Rules.

a. Because the Pharmacy and Medical Boards Have Not Approved the Substances to Be Injected as Statutorily Required, 16.4.15.12's Grant of Authority to Administer Substances by Injection Is Unlawful.

The Pharmacy and Medical Boards have not approved the items to be administered by injection (CHIRO 42-46), as required by § 61-4-9.2(B). However, 16.4.15.12 NMAC purports to authorize some of these items to be administered by injection if an APCP completes certain training, regardless of whether the Pharmacy and Medical Boards have approved these items for administration by injection. For example, 16.4.15.12(C) authorizes an APCP to administer dextrose, phenol, autologous blood, and platelet rich plasma by injection after completion of certain training. Therefore, the authority purportedly granted to APCPs by 16.4.15.12 NMAC is unlawful.

In regard to the Chiropractic Board's rule 16.4.15.7(E), which requires that items in the formulary have consensus, "as by statute," of the Medical and Pharmacy Boards, Appellee argues that no consensus is required for items listed in Subsection A to be administered by injection (Br. at 17); and alternatively, that

there was consensus, in that "the Chiropractic Board did incorporate many of Appellants' issues into the final formulary." (Br. at 18-19). Appellant ICA maintains that items listed in Subsection A to be administered by injection must indeed have the approval of the Medical and Pharmacy Boards. Appellant ICA maintains that any "general agreement and accommodation" (Br. at 18) by the Chiropractic Board does not rise to the level of formal approval by the Medical and Pharmacy Boards as required by statute. Furthermore, the Medical Board had expressly stated its disapproval of the items added to the formulary. CHIRO 42-46.

b. Statutory and Administrative Requirements for Certifying Advanced Practice Chiropractic Physicians Have Not Been Satisfied; Therefore, Any Additional Training Prescribed in 16.4.15.12 Is Insufficient.

Appellee argues that "ICA Appellant cannot provide a citation where the Medical Board is required under statute or rule to approve the content of the educational programs or alter the training hours..." (Br. at 20). Appellee admits that an "Advanced Practice Chiropractor must obtain extra training, such as a 'minimum of ninety clinical and didactic contact course hours in pharmacology, pharmacognosy, medication administration and toxicology' offered by an institution of higher education", and that the "institution of higher education cannot be a random school, it must be an institution approved of by the Medical Board." (Br. at 4).

Appellant ICA maintains that the newly adopted 16.4.15.12 NMAC

depends on the statutory requirements of §§ 61-4-9.1(D) and (E) being satisfied, which statutory requirements have not been satisfied. Section 61-4-9.1(D) provides the minimum educational requirements for a chiropractic physician to become an APCP. Under § 61-4-9.1(D), in order to become an APCP, a chiropractic physician must (in addition to other requirements) complete "a minimum of ninety clinical and didactic contact course hours in pharmacology, pharmacognosy, medication administration and toxicology ***certified by an examination from an institution*** of higher education ***approved by the board and the New Mexico medical board"*** (emphasis added).

Then, after completing the minimum ninety hours at an approved institution, §61-4-9.1(E) provides that an APCP must complete annual continuing education "as set by the [Chiropractic] board." The Chiropractic Board's own rule requires that APCPs seeking renewal of their certification registration shall have completed ten hours of continuing education "from an approved institution as stated in 16.4.15.8 NMAC." *See* 16.4.15.10 NMAC. This administrative provision refers to the institution of higher learning to be approved by the Medical Board. 16.4.15.8(B) NMAC. The newly adopted 16.4.15.12 NMAC prescribes additional educational requirements for the APCP who wishes to administer certain items. Under 16.4.15.12, APCPs are authorized to: administer vitamins

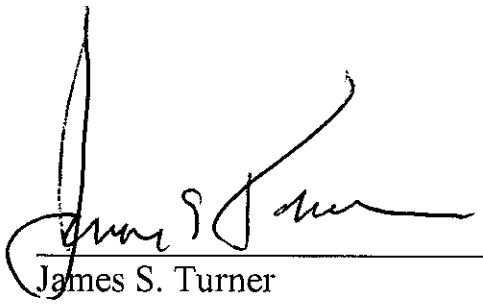
and/or minerals by IV administration after completion of a minimum of twenty-five hours of training in IV therapy; and administer certain substances by injection after completion of a minimum of fifty hours of certain training.

The relationship between § 61-4-9.1(D) - (E) and 16.4.15.12 NMAC may be viewed metaphorically as building blocks. The first part is the foundation; then, blocks may be laid on top of that. Without the foundation, the blocks cannot be laid. Here, § 61-4-9.1(D) – (E) provides the basic foundation: to obtain certification as APCP, and maintain that certification, a chiropractic physician must complete the minimum ninety-hour training, certified by examination from an institution approved by the Medical Board, and complete annual continuing education requirements for APCPs set by the Chiropractic Board. Then, if the APCP wants to administer certain substances and drugs, 16.4.15.12 provides for additional required training.

There is no evidence that the Medical Board has approved any institution to certify by examination the completion of the minimum education required by statute, nor the annual continuing education requirements. Since this statutory requirement of Medical Board approval of educational institutions has not been satisfied, the additional educational requirements in 16.4.15.12 cannot be sufficient to authorize any APCP to administer the substances and drugs items described in 16.4.15.12.

Dated: October 9, 2012

Respectfully submitted,



James S. Turner
Swankin & Turner
1400 16th Street, NW, Suite 101
Washington, D.C. 20036
(202) 462-8800; FAX (202) 265-6564

Charles V. García
Cuddy & McCarthy LLP
7770 Jefferson Street NE
Suite 305
Albuquerque, NM 87109
(505) 888-1335; FAX (505) 888-1369

Attorneys for Appellant

CERTIFICATE OF SERVICE

I certify that a true and accurate copy of the foregoing REPLY BRIEF OF APPELLANT, INTERNATIONAL CHIROPRACTORS ASSOCIATION was served via first class mail, on the 9th day of October, 2012, upon the following counsel:

Counsel for Appellee:

Zachary Shandler
Assistant Attorney General
New Mexico Attorney General's Office
P.O. Drawer 1508
Santa Fe, NM 87504-1508

Counsel for Appellant New Mexico Board of Pharmacy:

Gary K. King
New Mexico Attorney General
Mary H. Smith
Assistant Attorney General
111 Lomas Blvd. NW Ste. 300
Albuquerque, NM 87102

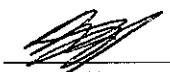
Counsel for Appellant New Mexico Medical Board:

Daniel R. Rubin
Special Assistant Attorney General
New Mexico Medical Board
2055 S. Pacheco, Bldg. 400
Santa Fe, NM 87505

Counsel for Amicus Curiae American Chiropractors Association:

Thomas R. Daly
Odin Feldman Pittleman PC
9302 Lee Highway Ste. 1100
Fairfax, VA 22031

Susan M. Hapka
Sutin, Thayer & Browne
P.O. Box 1945
Albuquerque, NM 87103



Michelle L. Zhang

Attorneys for Appellant