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Excepted Substances: A Comparison of Federal and State Laws

When a state adopts an act already written for Federal control, such as the Controlled Substances Act, there inevitably will be questionable provisions arising from the final product. The following is an example of one which may be applicable to several other states.

The Texas Controlled Substances Act (TCSA) was adopted by the state legislature in August 1973, following the format of the Federal Controlled Substances Act. The Act was divided into Schedules I-V and Penalty Groups 1-4. The Schedules set forth criteria for controlling possession, sale, and manufacturing offenses and the Penalty Groups set forth criteria for controlling possession, sale, and manufacturing offenses. (The Penalty Groups also determine which drugs may give rise to charges of Possession of Controlled Substance Paraphernalia Sec. 4.07 TCSA.)³

Federal Excepted Substances

The Federal Controlled Substances Act specifically defines and lists pharmaceutical preparations which are excepted from the application of all or any part of the Act. This list, published annually in the *Code of Federal Regulations—T21 [I]*, is an administrative action as specific criteria have not been established for exact definitions. For a preparation to be excepted from application of all or any part of the Act, an application must be made giving detailed information about the preparation. As set forth by Federal regulations, each application will contain the following information:

- (1) the complete quantitation composition of the dosage form,
- (2) description of the unit dosage form together with complete labeling,
- (3) a summary of the pharmacology of the product, including animal investigations and clinical evaluations and studies, with emphasis on the psychic or physiological (or both) dependence liability (this must be done for each of the active ingredients separately and for the combination product),
- (4) details of synergisms and antagonisms among ingredients,

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³Paraphernalia is limited to an instrument having in it any quantity (including a trace) of a controlled substance in Penalty Group 1 or 2 with intent to use it for administration of the controlled substance by subcutaneous injection in a human being. This change in Texas law had a dramatic effect in that it is no longer an offense to possess a pipe used for smoking marijuana or hashish.

- (5) deterrent effects of the noncontrolled ingredients,
- (6) complete copies of all literature in support of claims,
- (7) reported instances of abuse,
- (8) reported and anticipated adverse effects, and
- (9) number of dosage units produced for the past two years.

An exception may be revoked at any time pursuant to Section 202(d) of the Act [21 U.S.C. 812(d)].

Texas Excepted Substances

Schedule II Substances

Under Sec. 2.05(e) of the TCSA, any compound, mixture, or preparation containing

- (1) amphetamine,
- (2) methamphetamine,
- (3) methylphenidate, or
- (4) phenmetrazine

is excepted from the application of *all or any part of the Controlled Substances Act* (emphasis added) if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of these substances. Sec. 4.02(d) (6) (Penalty Group 3) of the Act states any compound, mixture, or preparation containing

- (1) amphetamine,
- (2) methylphenidate,
- (3) phenmetrazine, or
- (4) methaqualone

is excepted (emphasis added) if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of these substances.

Schedule III Substances

Under Sec. 2.05(e) of the TCSA, any compound, mixture, or preparation containing

- (1) allobarbital,
- (2) amobarbital,
- (3) aprobarbital,
- (4) butabarbital,
- (5) butalbital,
- (6) butallylonal,
- (7) butobarbital,
- (8) chlorhexadol,
- (9) cyclobarbital,
- (10) cyclopentenylallylbarbituric acid,
- (11) glutethimide,
- (12) heptobarbital,
- (13) hexobarbital,
- (14) ibomal,

- (15) lysergic acid,
- (16) lysergic acid amide,
- (17) methyprylon,
- (18) narcobarbital,
- (19) nealbarbital,
- (20) pentobarbital,
- (21) phencyclidine,
- (22) probarbital,
- (23) secobarbital,
- (24) sulfondiethylmethane,
- (25) sulfonethylmethane,
- (26) sulfonmethane,
- (27) thialbarbital,
- (28) thiopental, or
- (29) vinbarbital

is excepted from the application of all or any part of the Controlled Substances Act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentrations that vitiate the potential for abuse of these substances. Under Penalty Group 3 there is no provision for the above substances to be excepted.

Schedule IV Substances

Under Sec. 2.06(c) of the TCSA, any compound, mixture, or preparation containing

- (1) barbital,
- (2) chloral betaine,
- (3) chloral hydrate,
- (4) ethchlorvynol,
- (5) ethinamate,
- (6) methohexital,
- (7) meprobamate,
- (8) mephobarbital,
- (9) paraldehyde,
- (10) petrichloral, or
- (11) phenobarbital

is excepted from the application of all or any part of this Act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Sec. 4.02(d) (8) (Penalty Group 3) states that any compound, mixture, or preparation containing

- (1) barbital,
- (2) chloral betaine,
- (3) chloral hydrate,
- (4) ethchlorvynol,
- (5) ethinamate,
- (6) methohexital,
- (7) meprobamate,

- (8) mephobarbital,
- (9) paraldehyde,
- (10) petrichloral, or
- (11) phenobarbital

is excepted if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of these substances.

To incorporate the above-noted deviations of Schedules with the Penalty Groups and to be systematic with Federal Regulations the TCSA should provide an accurate legal definition of an excepted substance. Since the concept of the excepted substances of the TCSA was adapted from the Federal Controlled Substances Act, it should follow that only the excepted prescription drugs set forth by federal regulations should apply to the state level. Until this is accomplished, the laboratory must provide complete qualitative and quantitative analyses of all preparations, both pharmaceutical and illicit, subject to the excepted provisions under Texas law. Without complete laboratory results, there is room for erroneous indictments as well as possible acquittals on technicalities resulting from incomplete analyses.

Legal Effect of the Excepted Terminology

In Sec. 2.05(e) TCSA certain compounds, mixtures, and preparations are excepted from the applications of the Act. The question arises as to the extent of the exception and its applicability when considered with other portions of the Act. The wording taken by itself seems to have but one possible effect: that if the substance falls within the guidelines, the substance cannot form the basis for prosecution under the Act. The wording is as follows.

- (e) Any compound, mixture, or preparation containing any stimulant listed in Subsection (d) of Section 2.04 or depressant substance listed in Subsection (b) of this section *is excepted from the application of all or any part of this Act* if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system. [emphasis added]

The problem, however, as stated previously in this paper, is that some of the substances which are excepted from the Schedules through application of Sec. 2.05(e) above are not similarly excepted from the Penalty Groups. Although there are no cases which have been heard by the Texas Court of Criminal Appeals on this point, the rational interpretation of the wording "excepted from the application of all or any part of this Act" would leave no other alternative but to serve as an exclusion from the provisions of the TCSA. It would follow then that a substance which comes clearly under the Sec. 2.05(e) exception could not serve as the basis for prosecution under the portions of the Act proscribing possession, sale, manufacturing, or violations of either the sections dealing with fraud offenses or commercial offenses. This interpretation should hold for those substances which are excepted from the Schedules but not excepted from the Penalty Groups.

Although the wording is somewhat different, the exception set out in Sec. 2.06(d) contains the same essential terminology: "excepted from the application of all or any part of this Act." Again, the literal interpretation of this portion of the Act seems to require the same effect, that is to render those substances falling within this exception incapable of providing a basis for prosecution under the provisions of the TCSA.

Whether or not a substance falls within a similar exception set out in the Penalty Groups should not change the interpretation previously stated.

To compound a confusing situation, the wording contained in Sec. 4.02(d) (6) and Sec. 4.02(d) (8) setting out the excepted substances in the Penalty Groups is as follows:

(6) Any compound, mixture, or preparation containing any stimulant listed in Subsection (d) (1) of this section or depressant substance listed in Subsection (d) (2) of this section is *excepted*. . . (emphasis added)

(8) Any compound, mixture, or preparation containing any depressant substance listed in Subsection (d) (7) is *excepted*. . . (emphasis added)

Even though the exception herein stated does not as clearly define the scope of the exception as set out in Sec. 2.05(e) and Sec. 2.06(c), the rational interpretation of the wording would seem to imply that substances coming under these exceptions could not be used to support criminal actions under the Act. Again, there are those substances which are excepted under 4.02(d) (6) and 4.02(d) (8) and are not correspondingly excepted under Sec. 2.05(e) and Sec. 2.06(c). In spite of the lack of literal symmetry, the reasonable interpretation of the effect of the inclusion of these substances in the excepted category of the Penalty Groups would cause one to assume that prosecution based on one of these substances for any proscribed activity under the TCSA would be precluded.

Scientific Effect of the Excepted Terminology

From an evidentiary standpoint, an analysis for the controlled substance as well as an analysis for any active medicinal ingredient using the guidelines set forth under the exception provision of TCSA is required. In addition, the expert witness must offer testimony as to whether or not the excepted medicinal preparations vitiate the potential for abuse of the controlled substance by substantially decreasing the stimulating (or depressing) effect on the central nervous system based on the criteria set forth by Federal regulations. For an expert to be able to testify as to the stimulating or depressing effect on the central nervous system, or the lack thereof, the chemical analysis of the compound, mixture, or preparation submitted for analysis must show the quantitative results of the medicinal ingredients contained within.

If the compound, mixture, or preparation submitted for analysis is being questioned as to the possibilities of being excepted under the TCSA, it would require a *qualified opinion* of the expert witness as to whether or not that compound, mixture, or preparation has any potential for abuse and has any stimulant or depressant effect on the central nervous system.

If the substance is excepted under the TCSA and is a drug or device which bears the legend, "Caution: Federal law prohibits dispensing without prescription," or the legend, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," that is, a prescription drug, then such a compound, mixture, or preparation would fall within the provisions of Art. 4476-14, Vernon's Annotated Civil Statutes, Sec. 2(a) and be classified as a "Dangerous Drug," which is altogether a different Act following different guidelines.

Summary

A state law has placed an obligation on the criminal investigation laboratories to screen and quantitate all preparations, both pharmaceutical and illicit, that fall under the provisions of "Excepted Substances." Without complete screens on these preparations, there is room for erroneous indictments as well as possible acquittals on technicalities.

References

- [1] *Code of Federal Regulations—T21*, "Food and Drugs," Part 1300 to end, revised 1 April 1974, Office of the Federal Register, National Archives and Records Service, General Services Administration, Wash., D.C., pp. 84-94.

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