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Appendices

Appendix

I. Controlled Substances

Controlled Substances are a special class of prescription drugs. For the sake of regulation, controlled substances are classified into five groups or â€œschedulesâ€ based on 1) whether they have an accepted medical use; 2) their relative potential for abuse; 3) the degree of dependence that may be caused by abuse of the drug. Originally controlled substances referred to narcotic drugs exclusively, hence the term narcotics is a commonly used term. The classification of controlled substances has over the years been broadened to include other dangerous drugs as defined by the US Food and Drug Administration (US FDA). For more information see: http://www.deadiversion.usdoj.gov/schedules/schedules.htm

A. Definition of Schedules for Controlled Substances

1. **Schedule I (CI):** The drug or other substance:
   - has a high potential for abuse,
   - has no currently accepted medical use in treatment in the United States, or
   - has no accepted safe use under medical supervision.

   Examples: heroine, marijuana and a host of designer-drugs
2. **Schedule II (CII):** The drug or other substance:
   - has a high potential for abuse,
   - has a currently accepted medical use in treatment in the United States, or
   - has a currently accepted medical use but with severe restrictions, and
   - abuse of the drug or other substances may lead to severe psychological or physical dependence.

   Examples: morphine, oxycodone, hydromorphone, meperidine, codeine, anabolic steroids
3. **Schedule III (CIII):** The drug or other substance:
   - has a potential for abuse less than the drugs or other substances in schedules I and II,
   - has a currently accepted medical use in treatment in the United States, and
   - abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

   Examples: hydrocodone, codeine and others in combination with other drugs
4. **Schedule IV (CIV):** The drug or other substance:

- has a low potential for abuse relative to the drugs or other substances in schedule III,
- has a currently accepted medical use in treatment in the United States, and
- abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

  Examples: benzodiazepines (Valium, Ativan, etc), propoxyphene combinations

5. **Schedule V (CV):** The drug or other substance:

   - has a low potential for abuse relative to the drugs or other substances in schedule IV,
   - has a currently accepted medical use in treatment in the United States, and
   - abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

   Examples: Diphenoxylate combination, cough syrups

II. Pregnancy Categories

The pregnancy category of a pharmaceutical agent is an assessment of the risk of fetal injury due to the pharmaceutical, if it is used as directed by the mother during pregnancy. It does not include any risks conferred by pharmaceutical agents or their metabolites that are present in breast milk.

Pregnancy Category A

The pregnancy category of a pharmaceutical agent is an assessment of the risk of fetal injury due to the pharmaceutical, if it is used as directed by the mother during pregnancy. It does not include any risks conferred by pharmaceutical agents or their metabolites that are present in breast milk.

Pregnancy Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies which have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.

Pregnancy Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Pregnancy Category D

There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Pregnancy Category X

Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.