

# fact sheet

## DRUG SCHEDULING

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**How is scheduling determined?** The Food and Drug Administration (FDA) reviews a company's New Drug Application and, when appropriate, passes its recommendation to the National Institute on Drug Abuse (NIDA) for confirmation/acceptance. If accepted, the FDA and NIDA send a joint document to the Drug Enforcement Administration (DEA) for review. The result of DEA's review is the issuance of the proposed rule in the Federal Register.

**What is the list of schedules?** The Controlled Substances Act (CSA) requires that certain drugs be placed in one of five schedules, based upon medical value, safety and potential for abuse or addiction:

- **Schedule I** is reserved for drugs or other substances that have no currently accepted medical use and a high potential for abuse. Some Schedule I substances are heroin, LSD and methaqualone.
- **Schedule II** is reserved for drugs or other substances that have a currently accepted medical use and a high potential for abuse. Schedule II substances include FENTORA<sup>®</sup>, ACTIQ<sup>®</sup>, morphine, methadone and methylphenidate (Ritalin<sup>®</sup>).
- **Schedule III** is reserved for drugs or other substances that have a currently accepted medical use and a potential for abuse less than drugs or other substances in Schedules I and II. Their use may lead to moderate or low physical dependence or high psychological dependence. Anabolic steroids, codeine and hydrocodone with aspirin or Tylenol<sup>®</sup>, and some barbiturates are Schedule III substances.
- **Schedule IV** is reserved for drugs or other substances that have a currently accepted medical use and a potential for abuse less than drugs or other substances in Schedules II and III. Their use may lead to limited physical dependence or psychological dependence relative to drugs or other substances in Schedule III. Included in Schedule IV are Ambien<sup>®</sup>, PROVIGIL<sup>®</sup>, NUVIGIL<sup>®</sup>, Darvon<sup>®</sup>, Sonata<sup>®</sup>, Valium<sup>®</sup> and Xanax<sup>®</sup>.
- **Schedule V** is the classification used for the least dangerous drugs. These drugs or substances have a currently accepted medical use. Their use may lead to limited physical dependence or psychological dependence relative to drugs or other substances in Schedule IV. Certain over-the-counter cough medicines with codeine are classified in Schedule V.

The Controlled Substances Act also provides a mechanism for substances to be controlled, added to a schedule, decontrolled, and removed from control, rescheduled or transferred from one schedule to another.

**From the prescribing perspective, what is the difference between Schedule II and Schedules III and IV?** According to the DEA, a Schedule II drug has a 30-day prescription length and one needs a new prescription for refills; Schedule III and IV drugs have no mandatory controls on length of prescription (insurers may limit), and one can receive five refills in six months.

For additional information regarding the scheduling of a drug, go to [www.dea.gov](http://www.dea.gov).

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