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Dear Rick:

My harvest for the MDMA hearing from books and treatises on medical malpractice was meager, and I was also discouraged by what seemed to me the strong legal case presented in the government brief you sent. I am surprised that you are confident the judge won't accept the government's argument on the definition of accepted medical use and safety. In the medical malpractice literature I found no case directly on this issue, but from what I saw it seems very likely to me that state courts in malpractice cases would regard FDA approval as at least part of the definition of accepted medical use. I assume this because the use of an approved drug in the wrong dosage or for the wrong diagnosis is regarded as malpractice. Of course, there is not even an accepted diagnosis for the use of MDMA. The possibility that some therapists using MDMA may have been in violation of FDA regulations adds to the doubt about accepted medical use. But I'll pass on to you the little I found that might be helpful.

The standard of good medical care in malpractice cases generally includes: 1. reasonable or ordinary degree of skill and learning of a practitioner who is of the same school as the defendant. 2. Defined by skills common to the profession. 3. Defined by the standards common in the same locality or a similar one--this is now turning into a national standard, which would almost certainly apply in the case of drugs. 4. Good judgment. A reference on this is Michael V. Roberts, 91 New Hampshire, 499/23 A Second 361 (1941).

Breach of duty to the patient may include the use of a wrong drug or improper administration. The physician must possess the degree of knowledge and skill and exercise the degree of care, judgment and skill that other doctors of good standing of the same school or practice usually exercise in the same or similar

localities in the same or similar circumstances.

Baldor V. Rogers, 81 SO Second 658 (Flordia 1955): A doctor treated a cancer patient with drugs instead of the traditional surgery or x-rays. The court declared that "One man should not be condemned from the fact alone that he choses a weapon that another may consider a reed." The original of that case was 55 AL Second 453 (Florida 1955). This case established that a practice that was accepted by a "respectable minority" of practitioners was acceptable.

Here is another case. Bruce V. U.S. 167 FSupp. 394 (District Court Pennsylvania, 1947): Where there is no established or accepted procedure this does not become part of the negligence liability. If there is a difference of opinion, the defendant cannot be held negligent if he followed "a course recognized and approved by reputable physicians of good standing." And also if established treatments don't work.

A physician can protect himself from the charge of departing from accepted practice by getting informed consent to treatment as an experiment. This does not absolve him from reasonable care and diligence, but it covers departure from accepted practice. Experimental drugs should have reputable sources with written information on animal experiments, contraindications, side effects, safety, etc. (It seems that experimental use is by definition not accepted use).

The FDA is limited to interstate commerce, but this has been interpreted broadly. Shipping a new drug in interstate commerce without a new drug application violates the Food, Drug, and Cosmetic Act of 1938 as amended in 1962. "New" means "not generally recognized among experts as safe for use under the conditions prescribed or has become so recognized but which has not been used to a material extent or for a material time." This is quotation with some ellipses from 201p of the Food, Drug, and Cosmetics Act.

From a treatise on medical malpractice, David W. Louisell and Harold Williams, Medical Malpratice, Vol. II, Matthew Bender, New York, 1985 (original edition 1960): "Psychiatry, more than any other profession, apparently offers numerous schools of thought concerning how a particular condition should be treated... in determining the course and method of treatment, a psychiatrist, by necessity, must be permitted a wide range of discretion and judgment." And they cite Gregory vs. Robinson, 338 Southwest Second 88 (Missouri 1960).

Hood vs. Phillips 537 Southwest Second 291, 29. (Texas Civil Appeals, 1976): A physician is not guilty of malpractice when the method of treatment used is supported by "a respectable minority of physicians."

Another quotation from Louisell's treatise: "Psychiatry by definition involves human research and experiment: new psychotherapeutic techniques simply cannot be tested first on laboratory animals." (This is probably not much use in the definition of accepted medical use).

Drugs labeled "Caution--new drug" can be prescribed at discretion before proof of safety. (21 U.S. CA 355; 21 CFR 130.3).

Finally, I found one thing that might be helpful in the hearings before the House Ways and Means Committee on the Controlled Dangerous Substances, Narcotics and Drug Control Laws, 91st Congress, Second Sesssion, July 20, 21, 22, 23 and 27, 1970 (HR 17463):

John E. Ingersoll, Director of the Federal Bureau of Narcotics (I think), testifying on page 207, says "We recognize that the Secretary (referring to the Secretary of HEW) must make the necessary medical and scientific determinations which shall be determinative on the Attorney General in terms of keeping a drug from being brought under control....However, the converse is not true...."

If there is anything in here you would like me to follow up on, or anything else it would be useful for me to check out, please let me know.

Happy Holidays,

Jake

James Bakalar

JBB:EFG