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Controls Over the Manufacture of MDMA

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Inasmuch as MDMA may be a very useful psychotherapeutic adjunct, it is lamentable that it has reached the drug culture, because this has increased its potential for abuse as well as public health concerns. However, there are other issues that are being lost in the rhetoric about the government's scheduling decisions.

Of primary concern is the manufacturing process of the MDMA that is administered to patients. Ethical pharmaceutical manufacturers must adhere to strict standards that are set and monitored by the Food and Drug Administration (FDA). These standards address purity, stability, dosage, consistency and bioavailability of drugs that are administered to individuals for therapeutic purposes. Does anyone seriously maintain that producers of MDMA in private laboratories adhere to the standards of drug manufacturing that patients can reasonably expect from ethical pharmaceutical manufacturers? Did patients who were administered MDMA know that they were taking a dosage form of a drug that was not manufactured to generally accepted industry standards? What were patients told about the risks of adulteration associated with such uncontrolled home-brew manufacturing?

As a separate issue, how can scientists accept the merit of uncontrolled research based on the administration of drugs of undocumented purity and bioavailability? What is so special about MDMA that research should have circumvented the safety conventions normally required for new drug development? Without doubt, these conventions would be imposed on any ethical pharmaceutical manufacturer. For example, where is the data on the toxicity, carcinogenicity, mutagenicity and pharmacokinetics for MDMA?

It seems apparent that the duplicitous activity of investigators of this drug to avert the rigors of Investigational New Drug and New Drug application procedures established by the FDA contributed to the most recent government controls. MDMA was first misused by clinicians who sought to avoid the discipline, and perhaps expense, of conducting controlled clinical trials. The lesson, which should have been learned from LSD, is that research on compounds of this nature must be conducted conservatively and seriously, using protocols with valid measures of safety and therapeutic outcome.

Given the nature of uncontrolled efficacy research outside the milieu of peer review and analysis, governmental interference was not only inevitable, it was necessary. That investigators conducted several years of unhampered home-brew research occurred only because of the government's reluctance to interfere in the practice of medicine. There are several questions that are pertinent to this issue: (1) Are these controls only necessary when a drug is destined for commercial marketing?; (2) Are these studies only necessary to establish safety and effectiveness for a government review?; and (3) Are not all these standards derived from ethics of medical research?

It takes time, resources and dedicated people to conduct careful, clinical, controlled research that conforms to existing laws that govern human research and that follow established conventions of safety and scientific rigor. To do so, not only will keep a drug available for legitimate

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research, but it will also obviate the need for additional governmental controls.