The FDA medicine approval process represents the best way to help ensure that safe and effective new medicines are available to patients in need of appropriate medical therapy. It is important and appropriate to use the same scientific standards in the development and assessment of any drug.

The FDA is responsible for the regulation of all drugs intended for human use. The Agency reviews drug product applications to determine whether drugs are safe and effective for their intended uses. Any product that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is classified by FDA as a drug. This applies, regardless of the product's form, the product's active or inactive ingredients, or the way in which the manufacturer chooses to market and label the product.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that drugs be shown to be safe and effective for their intended uses before being marketed in the United States. In approving a drug for marketing, FDA reviews important information about the drug, including:

1. The indication for which the drug has been shown to be effective at treating, including specific uses in children or the elderly, if any.
2. What patients may benefit from its use, including information about whether the drug has been tested in children.
3. What adverse effects have been reported for individuals taking the drug.
4. How the drug should be taken (e.g., orally, intravenously).
5. The dose of the drug that is recommended to be used.
6. How the drug is made (e.g., as a pill, liquid) and what is in the drug, including both active and inactive ingredients.

It is our position that any marijuana product intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body" that has not been approved for marketing by the federal Food and Drug Administration it is neither safe nor effective and puts patients at risk. Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)].

Before the development of modern pharmaceutical science, the field of medicine was fraught with potions. There were as many anecdotal stories about these potions as there are today about marijuana. Many people were convinced that these potions helped them; however, many of these potions were absolutely useless, or conversely, were harmful to unsuspecting ill people. Thus evolved our current FDA drug approval process. The FDA process has protected us for 100 years; it is dangerous to undermine it.

A number of states have approved marijuana as a medicine. They have ignored the FDA process and made these decisions based on anecdotal reports. The anecdotal reports regarding "medical" marijuana are not reliable scientific evidence because the claimed benefits were not independently verified and do not reflect double-blind controls.

The anecdotal reports may also be inaccurate due to the emotional expectancy of the person using marijuana and the placebo effect. In some cases there may be deliberate exaggeration for ideological reasons.

Marijuana is intoxicating, so it's not surprising that sincere people report relief of their symptoms when they use it. They may be feeling better - but they are not actually getting better. They may even be getting worse due to the detrimental effects of marijuana.

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