Letter to the Editor: A Packaging Prescription for Medical Marijuana

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A number of critical factors for package design effectiveness are being overlooked as medical marijuana is being commercially introduced. Considerations must balance the inherent needs and behaviors of ill patients and recreational consumers along with the persistent, relentless, and focused determination and curiosity of children, who innocently mimic adult behavior.

Instead, obligation, guilt, and liability appear to be the driving factors for child-resistant packaging rather than a sincere concern about the hazards of accidental ingestions.

When ingested, Delta-9-tetrahydrocannabinol (THC) immediately enters the bloodstream and acts upon specific molecular targets on brain cells. The highest density of cannabinoid receptors is found in parts of the brain that can influence time perception and coordinated movement, such as that required to re-secure a bottle, or even remember to do so.

To alleviate safety concerns of the public regarding the sale of legalized marijuana, recent legislation in Washington and Colorado requires that marijuana sold in dispensaries be packaged in child-safe containers. Most of the current attention to child-resistant packaging came from realization that the Poison Protection Packaging Act of 1970 was originally enacted after accidental child ingestions of aspirin. Fifty years ago, 400 children died yearly from unintentional poisonings owing to the absence of special packaging. Today that number has been reduced to about 40 child deaths each year from unintentional poisonings.

The list of hazardous substances in need of special packaging has grown to include a number of controlled substances and all prescription drugs unless granted exemption. THC is a hazardous substance that is being approved by states as a medical substance available through prescription at retail outlets without FDA approval. The State of Colorado has passed legislation legalizing medical marijuana with a vague reference that marijuana must leave a dispensary in a child-resistant container. The Consumer Product Safety Commission definition per the Code of Federal Regulations 16 Part 1700.3(2) states: “That the special packaging to be required is technically feasible, practicable, and appropriate for such substance.”

It seems ludicrous that states would require that medical marijuana meet the standards of this federal protocol without requiring FDA approval of marijuana. It also seems absurd that they would take this stance without any consideration for the “appropriate” package for THC. Meeting the obligation of liability for child resistance falls far short of meeting the need of the patient. There is a child’s life and welfare to be considered as well as the patient’s ability to adhere to a precise regimen. Not all packages that pass the CPSC protocol are necessarily appropriate for the intended product.

From birth to 5 years old and beyond, a child’s essential means of discovery is to place the unknown in his or her mouth. If the regimen for administering THC were strictly to smoke flower-based marijuana,

there would potentially be a lower risk to children because they are not inclined to ingest a dry, shredded green-and-brown mix of leaves, flowers, stems, and seeds from the hemp plant, let alone smoke it. But as a medical substance, synthetic cannabis will also eventually be commercially available as tablets and capsules. Dronabinol is the only U.S. FDA-approved synthetic cannabinoid. It is often marketed as a legal pharmaceutical alternative to natural cannabis for cancer patients suffering from severe nausea and vomiting.

In addition, there is a distinct difference in distributing recreational marijuana as opposed to medicinal marijuana. Medicine as a substance must have well defined and measureable ingredients, and this consistency determines a patient's therapeutic dose and frequency. With recreational marijuana, one is not concerned about milligrams per dose or the therapeutic levels of active drug in the bloodstream. There is no prescribed regimen based on clinical trials and fact-based history.

From January 2005 to September 2009, of 790 children under the age of 12 screened for marijuana, none were found to be positive for exposure to marijuana. From October 2009 to December 2011, when medical marijuana expanded in Colorado, 14 of 588 children tested positive for marijuana exposure. The median age in the 14 patients was 3 years according to an abstract of the research published in the journal Clinical Toxicology. Although none of these 14 died, children are at risk for serious medical consequences. Prescribed dosages of THC can be between 4 and 12 milligrams for children ages 2 to 4, based on body surface area. Some "edibles" such as cookies and brownies contain 300 milligrams of THC.

Although the retail industry claims support for the child-resistant initiatives being recommended in Colorado, they seem to be less than dedicated to full commitment. The Medical Marijuana Industry Group states that larger locking bags for transport home would "solve most safety problems". But there is a resistance to tamper-evident features because of concerns that employing smaller tamper-evident bags would create a landfill problem and unnecessary cost.

A recent article exalting the value of bottles manufactured by a packaging supplier inaccurately states that its bottles have been "approved" by the United States Consumer Product Safety Commission. But the CPSC does not prescribe or endorse any specific package.

The packaging requirement for medical marijuana exceeds that for other controlled substances requiring special packaging. The package must be intuitive and easy to use. It is not enough to pass CPSC protocol. It must be a package that patients want to use in their home. There can be no exemptions such as we now grant to the elderly or debilitated. Because THC acts directly upon those brain cells called cannabinoids that influence memory, thinking, concentration, time perception, and coordinated movement, which are all required to properly open and re-secure a medical vial package for safety and adherence, packaging design must address impaired coordination and difficulty with thinking, concentration, and problem solving. These packages are commercially available, although not as extensively distributed as they should be.

The perplexing challenge is that a vast majority of legislators, manufacturers, and packaging professionals now getting involved are unfamiliar with the ramifications of and justification for special packaging. Some are apparently even confusing tamper evidence with child resistance.

And this issue is not limited to Colorado. Alaska, Arizona, California, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Virginia, and Washington have also passed legislation legalizing medicinal marijuana. And in California, Colorado, New Mexico, Maine, Rhode Island, Montana, and Michigan, pharmacies may sell medical cannabis.

It is highly recommended that state protocols be written instead of trying to adapt a federal protocol for a product not federally approved. In that way, the standards will be more appropriate to the risks involved with packaging THC as a capsule or tablet as well as when dispensed as a plant.

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