Cannabidiol (CBD) The Coming Crisis

David C. Steinberg, FRAPS

Steinberg & Associates, Inc.

Cannabidiol

- CAS # 13956-29-1
- Commonly called CBD
- 2-[(1R,6R)-3-Methyl-6-(1-methylethenyl)-2 cyclohexen-1-yl]-5-pentyl-1,3-benzenediol (IUPAC/CAS)
- Structure

Pure CBD



Legal Drug Uses

- Epidiolex®
- Approved by the FDA 6/25/18 for two rare and severe forms of epilepsy
 - Lennox-Gastaut syndrome and Dravet syndrome
- Consists of CBD with Inactive ingredients: dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose.
- Not stable after being opened 12 weeks.
 - Taken orally by syringe
- Now available by prescription only, at pharmacies.
- CBD Oil may or may not contain CBD! It is not defined or approved by the FDA and the term CBD has become generic in use

Other Uses of CBD

- Foods
- Dietary Supplements
- Cosmetics
- Unapproved drugs

The Crisis

- What is CBD?
- Specifications (solvents?)
- Purity
- Contaminants-THC
- Trace contaminants-pesticides, heavy metals
- Uses-Product claims
 - Unapproved imitations of Epidiolex® with possible disaster consequences.

Stability of CBD (pure)

- Heat-maximum temperature is 25° C (77 °F)
- Cold-Problems below 4 °C (39 °F)
- Light-package in dark brown glass
- pH-most stable 6.5-7.0

- Degradation products include THC!
- Stability testing of finished products becomes a problem.
 - Epidiolex instructions are to discard 12 weeks after opening.

Conclusions

The Agency needs to act ASAP to establish the specifications and requirements for <u>all uses</u> of CBD.

The major concern is the approved drug use.

But search CBD on the web and you will be overwhelmed by the number of hits and claims.

Caveat Emptor is not sufficient. Dr E.R. Squibb in trying to create a government agency to regulate drugs was supposed to have said: we need a good cop on the corner or the snake oil salesmen will drive real and safe drugs off the market.

Suggestion: Labels of All non-Drug Products with CBD

% CBD present (not added, but by analysis)

Date of manufacture of the CBD