

# Medical Products Update



Cynthia Culmo, R.Ph.

847.274.4782

[Cynthia.Culmo@av.abbott.com](mailto:Cynthia.Culmo@av.abbott.com)

# Federal

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- THC has been approved by the US Food and Drug Administration (FDA) for the following medical purposes:
  - Relieving chronic pain and spasticity
  - Stimulating appetite in patients with AIDS or who have undergone chemotherapy
  - Treating glaucoma
  - Treating nausea caused by chemotherapy in cancer patients

# Potrepeneur Dave of Goodies Green Label interviewed by MARY JANE, --- based in pot-friendly Seattle, WA

- ❑ Makers of fine medicated cookies, lasagna and other treats for Medical Marijuana patients:
  - Brownies and Italian food:
    - ❑ **Medicated** entrees: meatballs, manicotti, stuffed shells, lasagna. All these **premedicated** for people.
    - ❑ Alcohol tinctures
    - ❑ **Medicated** butter, olive oil, canola oil & vegetable oil

**Goodies Green Label  
Always Fresh,  
Always Potent!**

Garden fresh organic pasta sauces

Double dark chocolate brownies

Sugar free chocolate cookies

Peanut butter fudge

Peanut butter chip cookies

Double chocolate fudge

Cafe Mocha brownies



# Dosage from Goodies Green Label

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- “We all know that edibles are the best way to ingest pot if you want to save your lungs, but dosage questions?”
  - GGL: *“As long as the dosage remains constant with the people that bake the goodies for you, you can gauge your dosage. **It’s very difficult to specify a dosage for somebody else because you don’t know their tolerance.** So what I tell people is that to figure your dosage out, start with a ¼ of a cookie or brownie, because they are very potent, and wait an hour, hour and half, and see what that does to you. And then you can gauge your dosage from there.”*

## Dosage continued...

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- "Here's what we do with our products: **we size** our cookies, our fudge, and our brownies specifically so that **the dosage is exactly the same in a cookie as it is in a piece of fudge as it is in a brownie as it is in a muffin.** And because we **grow our own medicine** for baking, the **potency of each batch is consistent** as well. It's all metered, so everything remains constant."

# New products at GGL

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- Café Mocha: “the coffee gives it a great flavor, but the caffeine gives it an extra boost to people who want to *medicate in the morning but also want to get on with their day*. We put the coffee in there to counteract the knock-out effect”
- PART 173 SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION
  - Caffeine + marijuana = Approved combination drug? Combination product?

# GRAS?

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- ❑ Recent FDA publication: The federal agency said that it does not consider melatonin to be safe food additive and that brownies are “adulterated” because they contain it. Same for marijuana?
- ❑ Sen. Dick Durbin, D-Ill., the No. 2 Democrat in the Senate, has pressured the FDA to clarify its policy on foods that contain dietary supplements.
- ❑ Melatonin, but is marijuana a dietary supplement now?

**Goodies Green Label** Well I think I have tried enough of the "Goodies Green Label" line and have sufficiently awakened from the resulting coma, to comment on their products. The first thing you have to get over is the actual size of the goodies...they are literally 4.5" across and 1/2" thick (I put a tape measure to them) and they weigh approx. **102 grams each**. That's the cookies, the fudge is just as massive at 2" x 2" and are 1 1/4" thick and they weigh approx. **105 grams each**. Yeah so they're big but, you're wondering how they taste...I have a real affinity to peanut butter fudge and I have never tasted a better fudge....sorry Aunt Lena but, that's how it is. The double chocolate fudge was incredibly delicious as well and the double chocolate chip cookies with milk chocolate and white chocolate chips are more than just a mouthful to say, they are absolutely incredible. Of course the definitive factor would be the potency, I can sum it up by saying, **if these treats get out to the masses** we'll be seeing **"Don't Eat and Drive" public service announcements**. Why can't all companies take the same pride in their products as "Goodies" does with theirs?

Ok, so some of you have realized that I might have a vested interest in seeing the "Goodies" line in every ones cupboard....I'm the manager of Evergreen Holistic Center and yes we carry "Goodies Green Label" in the shop. Of course, I'd prefer you all came into our shop to **get *all your meds*** but, it doesn't matter where you get those "Goodies Green Label" goodies...just go get 'em!!!

Alright!!! I forgot about the pasta sauce and the lasagna.....and it's almost dinnertime!!! From [EHC](#) Junior Member – GGL Blog 7/23/10, 3:18pm



# Batch manufacturing

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- GGL: "The consistency of the butter changes when you put that medicine in it. Every dose, every batch that we make is prepared individually."
  - Compliant to 21 CFR Part 101 Sec. 101.67 Use of nutrient content claims for **butter**?: "...The product **may contain safe and suitable** ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness..."

# States Activities

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[Alabama](#) | [Alaska](#) | [Arizona](#) | [Arkansas](#) | [California](#) | [Colorado](#) |  
[Connecticut](#) |  
[Delaware](#) | [Florida](#) | [Georgia](#) | [Hawaii](#) | [Idaho](#) | [Illinois](#) | [Indiana](#) | [Iowa](#) |  
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Hampshire](#) | [New Jersey](#) | [New Mexico](#) | [New York](#) | [North Carolina](#) | [North  
Dakota](#) | [Ohio](#) | [Oklahoma](#) | [Oregon](#) | [Pennsylvania](#) | [Rhode Island](#) | [South  
Carolina](#) | [South Dakota](#) | [Tennessee](#) |  
[Texas](#) | [Utah](#) | [Vermont](#) | [Virginia](#) | [Washington](#) | [West  
Virginia](#) | [Wisconsin](#) | [Wyoming](#)

# States and Washington, D.C. – medical marijuana is legal-

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- Alaska
- Arizona
- California
- Colorado \*
- Delaware
- Hawaii
- Maine
- Maryland
- Michigan
- Nevada
- New Jersey
- New Mexico
- Oregon
- Rhode Island
- Vermont
- Washington, D.C.

\* - edible marijuana is legal.

# Colorado

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- June 2, 2011: Colorado Gov. John Hickenlooper signed into law several changes to the nation's most exhaustive medical marijuana regulations
  - **A law setting labeling standards for edible cannabis products such as pot brownies.**

# State vs. Federal

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- ❑ Federal attorneys in Colorado and other marijuana states have warned state authorities that they're putting state employees at risk of federal drug prosecutions when they regulate marijuana, which is illegal under federal law.

[WSJ-Stephanie.simon@wsj.com](mailto:WSJ-Stephanie.simon@wsj.com)

## COLORADO'S MEDICAL-POT RULES

Nov 23, 2010

- “For years, the only discussion was, “How long should we lock people up for possessing marijuana?” said Brian Vicente, executive director of Sensible Colorado, a patient-advocacy group. **“Now we’re discussing what the font should be on the label of a medical-marijuana brownie.”**

# Passed/Failed 2011 Legislation re: Medical Marijuana

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## Passed:

- ❑ Delaware: Signed by Gov Markell on May 13, 2011, effective July 1, 2011
- ❑ Maryland: Signed by Gov O'Malley on May 10, 2011

## Failed:

- ❑ Alabama
- ❑ Connecticut
- ❑ Florida
- ❑ Idaho
- ❑ Oklahoma
- ❑ Texas
- ❑ Iowa
- ❑ Kansas
- ❑ Mississippi
- ❑ North Carolina
- ❑ West Virginia

# 6 States with Pending Legislation to Legalize Medical Marijuana (as of Aug. 4, 2011)

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- Illinois
- New York
- Massachusetts
- Ohio
- New Hampshire
- Pennsylvania

# Touted as Biggest new emerging market since the internet businesses of the late nineties

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- HempCon 2011, Los Angeles, CA  
Aug 26-28, 2011

## Associates:

- Blow Ya Mind Clothing
- Boldt Bags
- CD Seeds
- Calibis Clothing
- California Care Coop
- California Herbal Relief
- Cannabis Career Institute
- Cannabis Patients Alliance
- Cannacatering
- Cannaking Collective
- Capstone Analytics
- Chronic Candy
- Chronic Jerky
- Creative Business Network
- Creme de Canna
- Delta Health & Wellness
- Dynamite
- EC Inc.
- ECF Coop
- EJ Vapor Int.
- Earthly Body
- Elemental Wellness
- Elite Heat

# 10 Little Known Facts in the Medical Marijuana Debate ([www.procon.org](http://www.procon.org))

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- Marijuana is classified as a **schedule 1 drug** by the 1970 Controlled Substance Act, which means the Federal Government considers marijuana to have:
  - High Potential for Abuse
  - No Currently Acceptable Medical Use
  - A lack of Accepted Safety
    - Rescheduling marijuana to the less restrictive Schedule II or III remains a contentious issue.
    - There has never been a documented human fatality from overdosing on tetrahydrocannabinol or cannabis in its natural form – through 2005

## #2

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- The US government supplies **320-260 marijuana cigarettes monthly** to four seriously ill patients in the Compassionate Investigational New Drug (IND) program.
- The project began in 1978, but was closed to new patients in 1991.

# #3

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- **Marijuana was not reported as a primary cause of death at all** between Jan. 1, 1997 to June 30, 2005.
  - According to FDA data obtained by Freedom of Information Act (FOIA) request.

# #4

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- The states with the three highest possession limits among the 15 states with legal medical marijuana are Oregon, California, and New Mexico.



# #5

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□ **8** of the **10** states that had legalized medical marijuana by 2006 saw a **decrease in teen use** of marijuana from 1999 to 2006.

- Alaska

- California

- Nevada

- Oregon

- Montana

- Hawaii

- Wyoming

- Washington

# #6

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- Marijuana causes a series of cellular reaction in the brain that ultimately produce the “high” feeling.
  - Smoked or inhaled marijuana takes only a few minutes to reach the brain



- When eating or drinking marijuana, the process can take up to an hour.



# #7

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- When swallowing marijuana (in teas, brownies, etc), the main active ingredient, **Delta-9-THC**, is transformed by the liver into the more psychoactively powerful **Delta-11-THC**.



# #8

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- The University of Mississippi has grown marijuana (including a placebo with virtually no THC) for US government-approved research since 1968.
- Each year (depending on demand) the University grows:
  - 6.5 acres to 1.5 acres to none

# #9

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- A UCLA study found **no association between marijuana & lung cancer.** (the study also suggested that marijuana may even have “some protective effect.”)
- However, the British Lung Foundation report in Nov. 2002 that 3-4 marijuana cigarettes a day are as dangerous to the lungs as **20 or more tobacco cigarettes a day.**

# #10

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- The first cannabis-based prescription medicine, Sativex, was launched in the United Kingdom on June 21, 2010
  - Sativex is a mouth spray approved to treat spasticity (muscle tightness) in patients with multiple sclerosis.
  - Source: "Did You Know?" page, <http://medicalmarijuana.procon.org>  
ProCon.org



# Marketing to Children??

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- Mar 2011: ABC news reports that children in CA and IL have become ill in the last several weeks after eating cookies and brownies made with marijuana.
  - Sold in convenience store – clerk didn't know they contained marijuana. Labeling??

# Attractive to children?

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- ❑ Source: Dixie Elixirs & Medicals
- ❑ Medicated chocolate truffles by Colorado-based Dixie Elixirs & Medicals.
  - Despite the tempting fare, this stuff is not something one should binge on.



By Joseph Pisani  
*Posted Dec. 9, 2010*

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Carbonated drinks by Colorado-based [Dixie Elixirs & Medibles](#) come in seven different flavors, from sparkling pomegranate to blueberry to grapefruit. A bottle usually sells for about \$10 at medical marijuana dispensaries. A half bottle is the recommended dosage amount.



**Mile High Ice Cream** in Colorado makes ice cream flavors such as Brown Sugar Cinnamon Pot Tart, Birthday Baked and Ganja Mint Chocolate Chip.



Ganja Gourmet is a take out restaurant and dispensary in Denver, Colo. Serves everything from medical marijuana-infused pizza to lasagna to cheesecake.

When the restaurant first opened a year ago, patients were allowed to eat inside the establishment, but since then laws have prohibited on site consumption.



Pot goes tropical. These fruit lozenges, from [Dixie Elixirs & Medibles](#), come in flavors such as mango pineapple and orange. The company says that one should be enough to offer pain relief-  
for most patients.

The popcorn by Colorado-based Mile High Ice Cream

Five doses in one bag  
Comes in various flavors from Caramel Corn and Butter Corn.



Nancy B's Edible Medicine  
The Colorado-based company,  
founded by Jenelise Robinson, makes  
marijuana edibles: peanut butter cups, cupcakes  
and brownies  
Sold to dispensaries.



# Federal lawsuit

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- Sept 4, 2008: Michael Martin was to be sentenced [in Federal court] [for his involvement in "Tainted Inc." medical marijuana edibles]
- **"Judge Wilkin asked several astute questions about state law and the interplay between state law and federal law. Clearly, she saw that the conflicting laws made medical marijuana cases unique."**

# Regulations – what is edible medical marijuana?

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- ❑ Organic laws/regs?
- ❑ Medicine=drug?
- ❑ Food laws/regs? Federal & State
- ❑ Labeling?
  - Dosage versus serving size?
  - Expiration date versus Best Used By?
  - NLEA?
  - Dietary Supplement claim?

# 510K Changes

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- IOM report
- PEW Research
- AdvaMed
- Multiple Law blogs

Ahhhhhh..... another time, another conference!

**THANK  
YOU**

