

(not so) Fun CAM Facts

Richard Jaffe, Esq.

Ca. Office

770 L Street, Suite 950

Sacramento, Ca. 95814

916-492-6038

rickjaffeesquire@gmail.com

www.rickjaffe.com

IAACN

JACKSONVILLE, AUGUST 11, 2016

Topics

- FDA cracks down on API's in Supplements
- And compounders too
- A lot of Med. Boards are looking at advertising
- Your stem cells are unapproved new drugs
- Ca. (and maybe the Feds) give CBD a hard time
- Cali. and the Personal Belief Vaccine Exemption

FDA goes after API's in supplements

- Although FDA drug definition is functional, dietary supplements can't have API's (active pharmaceutical ingredients)
- If they do?
- Class 1 recall (\$\$\$) plus possible criminal prosecution
- FDA on warpath or many supp. manufacturers screwing up?

6/1/16 through 7/15/16: 30 Class 1 recalls

- Which API's?
- Desmethylsibutramine, Fluoxetine, Hydroxythiohomosil, denafil (an analog of sildenafil), Phenolphthalein, Salicylic Acid, Sibutramine
- Indications? weight loss, erectile dysfunction, and pain

COMPOUNDERS ARE TARGETED BIG TIME

- Old days, grey area, state pharmacy board control compounders. (prescriptions vs manufacturing)
- New England Pharmacy deaths (and others supposedly) causes 2013 DQSA which “clarified” FDA’s role. (read: control)
- Results?

Results

- Drop in inspections/warning letters against pharma except compounders.
- 3% of inspections result in warning letters, but for compounding pharmacies and outsourcing facilities, close to 40%,
- Of 42 warning letters in 2015, 24 were to compounders 3 to regular pharma (API's and Outsourcing were the rest).
- Bottom line: compounders are now a big time target of FDA and if they come, almost 100% get 483 observations and 40% chance of a warning letter; (and it may get worse)

Medical Board Activity

The good 'ol days: record keeping

Now: advertising. Why?

- The Web/Public complaints (open season)
- Easy statutes:
 - lack of substantiation, unreasonable expectations, false or misleading "in any respect," implied claims (e.g. chaparral)
- The dilemma? what to say? Follow the FDA?
But not best for business; disclaimers?

You cells are now unapproved new drugs

- History: same day autologous, not more than MM (Ok to separate), (sort of homologous)
- Stem cells in the wild west and claims
- Regenerative Sciences
- Warning letters/ guidance documents
- Sept. Hearing (sort of)
- Kirk bill is a joke
- The future

Problems for the CBD Folks

- Cali: closure by investigation:
- Medwest and Napa company
 - Mere Allegation of chemical extraction
 - Abuse of investigative process? Remedy?

FDA: IND equals no CBD oil as supplement?

(Stay tuned on that)

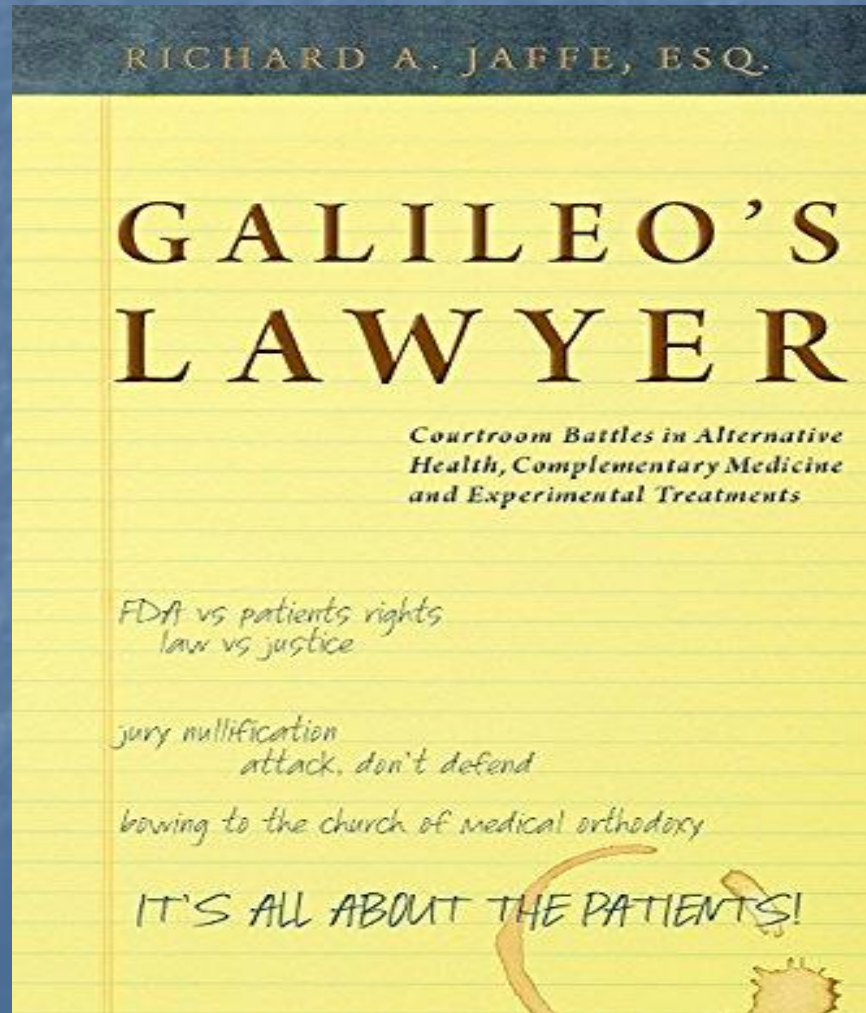
Cali. eliminates PBE

- Most states have PBE/religious exemption from vaccination
- Cali. Eliminated PBE last year
- Two lawsuits: state and federal
- Preliminary injunction hearing tomorrow
- Probable result: (technicalities matter, so does the world view)
- Problem with these actions.

Recent blog topics

- Cosmeceuticals
- Are stem cells over?
- Recent Stem Cell Legislation
- Board Subpoenas and de factor search warrants
- SB 277
- What's wrong with the US Health care system
- www.rickjaffe.com

Now on kindle (cheap)



Richard Jaffe, Esq.

California

770 L Street, ste. 950
Sacramento, Ca. 95814
916-492-6038
916-492-6039 fax

Houston

4900 Woodway, ste. 510
Houston, Tx. 77054
713-626-3550
713-626-9420 (fax)

cell: 713-857-8096

www.richardjaffe.com

rickjaffeesquire@gmail.com