10th Annual Food and Drug Law CLE

All Matters FDA:

Crimes, Misdemeanors and More...

COVID-19, Marijuana, Opioids, CBD, Vaping, Unsafe Pet Products, and Other Hot Topics . . .

Presented by the Delaware County Bar Association and Widener University Delaware Law School Food and Drug Law Association

Wednesday, October 21, 2020
1:00 p.m. – 4:00 p.m.

Delaware Law School

delawarelaw.widener.edu

Food and Drug Law CLE Symposium
Wednesday, October 21, 2020
1:00 – 4:10 p.m.

Welcome by **Christopher Mondics,** Moderator for the symposium

Speaker Introductions by **Jared M. Becker**, Food and Drug Law Association Board Member; **Christopher Mondics**, Legal Affairs Journalist; and **Professor Roseann B. Termini**, symposium Director

Order of Presentations:

Roseann B. Termini, Esquire, Food and Drug Law Legal Scholar; National Speaker; Teaches Food and Drug Law Courses, Widener University Delaware Law School: Ethics Rules, COVID-19, Vet., Vaping, Opioids, and other FDA Topics

Congressman Raja Krishnamoorthi, 8th District of Illinois: FDA topics especially related to COVID-19 (e.g. Emergency Use Authorizations- putting the brakes on issuance without any review)

Jessica J. Sleater, Esquire, Andersen Sleater Sianni LLC, New York, NY: Unsafe Pet Products

SHORT 10-MINUTE BREAK

Melissa A. Chapaska, Esquire, Cannabis Law PA, Harrisburg, PA: Medical Marijuana, CBD, Hemp

The Honorable John P. Capuzzi, Delaware County Court of Common Pleas, Media, PA: Drug Courts, Opioids

Edwin R. Thompson, President, PMRS, Inc., Horsham, PA: Opioids

Question and Answer Period

BIOGRAPHIES

The Honorable John P. Capuzzi Sr.

The Honorable John P. Capuzzi, Sr. was sworn in January 3, 2012 to a ten-year term on the Delaware County Court of Common Pleas. Judge Capuzzi earned a BA and MBA at LaSalle University. He obtained his Juris Doctor from the Delaware Law School of Widener University in 1988. Judge Capuzzi is admitted before the Supreme Court of the United States, the Pennsylvania Supreme Court, and the Federal Court for the Eastern District of Pennsylvania.

Judge Capuzzi is assigned to the criminal court division. Judge Capuzzi is the Chairman of the Criminal Justice Advisory Committee and the Administrator of the Second Chance Court Program.

Judge Capuzzi is a Life Member and Past President of Yeadon Fire Company No. 1. He served as President of Yeadon Borough Council from 1982 through 1989 and as the First Ward Commissioner for Marple Township from 2000 through 2005. Judge Capuzzi has served as President of the Guy G. de Furia American Inn of Court. In 2012, Judge Capuzzi was presented with the Guy G. de Furia Award in recognition of his outstanding legal ability, professionalism and high ethical standards.

From 1988 through 2005, Judge Capuzzi served as a Deputy Attorney General in the Torts Litigation Section of the Pennsylvania Office of Attorney General. During that time, he litigated major, complex cases for various state agencies.

Starting in 2006, Judge Capuzzi served as the Magisterial District Judge for Marple Township and Haverford Township. From 2006 to 2011, he was a partner in the law firm of Imperatrice, Amarant, Capuzzi & Bell, P.C.

As a practicing attorney, Judge Capuzzi was AV rated (highest legal ability and ethical standards) in Martindale Hubbell.

Melissa A. Chapaska, Esquire

Melissa Chapaska is an attorney at Hawke, McKeon & Sniscak LLP, a Harrisburg-based law firm, and is a part of the firm's medical marijuana practice group, Cannabis Law PA, where she assists medical marijuana growers, dispensaries, laboratories, and associated businesses with navigating the medical marijuana regulatory landscape, including through litigation and appeals before administrative agencies and appellate courts. Ms. Chapaska has published numerous articles and frequently lectures on issues affecting state-legal medical marijuana industries, including as part of a Pennsylvania Department of Health approved medical marijuana training provider. Additionally, Ms. Chapaska is a regular contributor to Pennsylvania Appellate Advocate (www.paablog.com), a resource for pending issues before Pennsylvania's appellate courts. Ms. Chapaska has served as YLD Liaison for the Pennsylvania Bar Association Medical Marijuana and Hemp Law Committee since 2017 and currently serves as Treasurer of the Dauphin County Bar Association's Government Law Section. She earned her B.A. from the University of Pittsburgh and her J.D. from Widener University Commonwealth Law School.

Congressman Raja Krishnamoorthi

Congressman Raja Krishnamoorthi was elected in November 2016 to represent the 8th District of Illinois, which includes the west and northwest suburbs of Chicago. Raja serves on the Oversight Committee, for which he is also the Chairman of the Subcommittee on Economic and Consumer Policy, as well as on the House Intelligence Committee. In addition to this committee work, Raja was selected as an Assistant Whip and serves on the Steering and Policy Committee.

Raja's policy platform focuses on growing and strengthening the middle class by supporting small businesses, rebuilding our infrastructure, and protecting Social Security and Medicare. Raja knows our economy works best when it works for all of us, and that's why he's fighting to make college more affordable, expand access to paid sick and parental leave, and guarantee equal pay for equal work.

Raja is the child of immigrants and was reared in Peoria, Illinois. He attended public schools in Peoria and was a valedictorian of his high school class. Scholarships and student loans allowed Raja to graduate *summa cum laude* from Princeton University with a degree in mechanical engineering and a certificate from the Princeton School of Public Policy. He then graduated with honors from Harvard Law School and clerked for a federal judge before practicing law in Chicago.

Raja pursued public service while practicing law and was appointed by Illinois Attorney General Lisa Madigan as a Special Assistant Attorney General to help start the state's Public Integrity Unit created to root out corruption in Illinois. As a member of the Illinois Housing Development Authority, Raja chaired its Audit Committee, helping to provide thousands of low and moderate-income families across the state with affordable housing. Raja also served as Illinois Deputy Treasurer. There, he oversaw the state's technology venture capital fund and helped revamp programs such as the state's unclaimed property program to become leaner and more efficient.

After his time in the Illinois Treasurer's Office, Raja returned to the private sector, serving as president of research-oriented small businesses developing technology in the national security and renewable energy industries. Raja also served as the Vice-Chair of the Illinois Innovation Council and co-founded InSPIRE, a non-profit that provides inner-city students and veterans with training in solar technology.

Raja and his wife, Priya, a physician, live in Schaumburg with their two sons and baby daughter.

Christopher Mondics

Chris Mondics is a Philadelphia-based journalist focusing on the law, national security and health care and is writing a book on the opioid epidemic. Earlier in his career, he was a correspondent for *The Philadelphia Inquirer* in Washington where he covered the White House, Capitol Hill and various federal agencies. In addition to the *Inquirer*, his work has appeared in the *Washington Post*, the *Los Angeles Times* and many other publications in the U.S. and abroad.

Jessica J. Sleater, Esquire

Jessica J. Sleater represents clients in complex litigation in federal and state courts across the country specializing in consumer and shareholder class actions. She represented toll road customers in a class action resulting in settlement payments of over $20 to class members in *Cohen v. F/ETCA, et al.* She represented shareholders in *N.J. Carpenters Pension Fund v. infoGROUP, Inc.*, No. 5334-VCN, 2011 Del. Ch. LEXIS 147 (Del. Ch. Oct. 6, 2011), resulting in a $13 million settlement. Her argument on behalf of bondholders in litigation against Argentina was profiled in the New York Times and the Wall Street Journal. She was counsel for plaintiffs/respondents in an appeal before the U.S. Supreme Court that resulted in an unanimous decision for plaintiffs in *Merck & Co. v. Reynolds*.

Ms. Sleater represents pet owners, who purchased pet food that led to the sickness and death of one of their dogs in the class action, *Mael, et al. v. Evanger's Dog and Cat Food Co., Inc. et al*. She also represents customers, who purchased hair products that were misrepresented and caused some to lose hair and scalp sores in *In re: Monat Hair Care Products Marketing, Sales Practices, and Product Liability Litigation*. In another class action alleging a racketeering scam, *Cisneros v. Petland, Inc.*, she represents customers, who purchased animals that were certified as healthy, but were not. She is also counsel for pet owners, who purchased a flea and tick medication that failed to warn of its health risks in *Palmieri v. Intervet. Inc.*

Ms. Sleater graduated with a B.A. *cum laude* from Truman State University and a J.D. from Saint Louis University School of Law. Ms. Sleater was selected as the Editor-in-Chief of the Saint Louis University Public Law Review. She is admitted to practice in the courts of the States of New York and Missouri, as well as the United States District Courts for the Southern and Eastern Districts of New York and the United States Court of Appeals for the Second Circuit. Earlier in her career, Ms. Sleater served as an Assistant Attorney General for the State of Missouri.

Ms. Sleater's articles on the legal industry have been featured in Law360 including The Rise of the Small Firm Class Action Business Model and Where are All the Women in the Plaintiffs' Bar? Ms. Sleater co-founded the Women's Entrepreneurial Plaintiffs Lawyers Network (wePLn), a group for women attorneys that seeks to foster collaboration, business development, and career growth. Super Lawyers recognizes Ms. Sleater as a New York Metro area "Super Lawyer."

Outside the office, Ms. Sleater volunteers with RAINN (the Sexual Assault Hotline) helping survivors of sexual assault. She has a rescue dog named Foxie.

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Roseann B. Termini, B.S., M.Ed., J. D.

Roseann B. Termini, B.S., Ed. M., J.D. has extensive experience in food, drugs, medical devices, personal care, dietary supplements, tobacco and veterinary products regulation. The reason Ms. Termini published recent comprehensive editions of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products* print and E-book formats is because a "light bulb went off" concerning evolving law, novel cases and latest regulations. There is a full E-book that mirrors the print, as well as 12 stand-alone separate subject specific E-books. Professional considerations, ethical issues, enforcement, criminal corporate liability and politics are covered. See: *www.fortipublications.com*

Other publications span a broad array of topics including the opioid epidemic, tobacco, vaping and e-cigarettes, right-to-request investigational therapies, corporate criminal liability, accountability, health claims, dietary supplements, product classification, duty to warn, preemption, promotion, stem cells, risk assessment, globalization, medical device safety and the Foreign Corrupt Practices Act. Her works are cited in other publications.

Ms. Termini is a featured speaker at international and national conferences and webinars including the Central Atlantic Association of Food and Drug Law Officials, the Pennsylvania Bar Institute (PBI), FDANews, the Food and Drug Law Institute and the Society of Cosmetic Chemists. She was selected to present at the Center for Ethics and Rule of Law Opioid Conference, was the sole speaker at a national opioid webinar and has been interviewed about this crisis. She also teaches none other than Food and Drug Law primarily online and values insights from her students.

Ms. Termini is the faculty conference director of the annual "*All Matters FDA*" symposium at Delaware Law School, Widener University that addressed topics such as COVID-19, Opioid Crisis, Marijuana, E-cigarettes, Food Safety, Claims, Foreign Corrupt Practices Act, Biosimilars, Dietary Supplement regulation, and Corporate Accountability. Presentations have included: *Opioids, GMOs, Personal Care Products, Medical Devices, Criminal Enforcement*, *Who Really Regulates Your Pizza, Are "Smart Labels" Really Smart and Terminology such as Natural.*

Her writing expertise led her to an appellate clerkship, position as sole corporate pharmaceutical counsel, regulatory affairs attorney and senior deputy attorney general at the Pennsylvania Office of Attorney General (OAG) where she prosecuted cases at the trial and appellate levels and spearheaded the implementation procedures for the Pennsylvania Plain Language Act. She was the first recipient of the "Plain English" Award by the Pennsylvania Bar Association. Who's Who recognized Ms. Termini's excellence in the field with the Lifetime Achievement Award.

Ms. Termini has been actively involved in committees of several professional associations for a number of years, including her service as Chair of a Food and Drug Law Institute Committee. She was appointed Co-Chair of the Pennsylvania Bar Association Health Law Committee and Vice Chair of the Disability Rights Committee. She served on the President's Council at Immaculata University and as Vice Chancellor of the Justinian Association. Ms. Termini was appointed to the Board of the St. Thomas More Law Society and is a member of the Central Atlantic Association of Food and Drug Law Officials. She was appointed Vice Chair, Phi Alpha Delta Chapter. Ms. Termini was admitted to the Bar of the United States Supreme Court.

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https://twitter.com/RoseannTermini
www.linkedin.com/in/roseanntermini/

Edwin R. Thompson

Horsham, PA 19044
ethompson@pmrsinc.com

About

Founder, owner, and President of Pharmaceutical Manufacturing Research Services, Inc. Forty-seven years' experience in pharmaceutical sales, marketing, product development, research and development, and manufacturing.

Inventor of 17 issued worldwide pharmaceutical patents.

Experience

PMRS, Inc.
1994 – Present

Greenwich Pharmaceuticals, Inc.
1986 – 1994

McNeil Pharmaceutical/Johnson & Johnson
1973 – 1986

United States Army Reserve
1973 – 1979
Sergeant First Class; Honorably Discharged

Education

Glassboro State College
Graduated 1972

Publications and Presentations

Citizen Petition from Pharmaceutical Manufacturing Research Services, Docket ID FDA-2016-P-0645, February 26, 2016.

> *Request FDA uniformly apply its standards for permitting a drug to be labeled as abuse deterrent by (a) requiring pre-marketing scientific proof of manipulation and extraction studies for abuse deterrent formulation in both small and large volume extraction and (b) requiring post-marketing empirical proof in the field of abuse deterrence before allowing a drug to be labeled abuse deterrent.*

https://www.regulations.gov/docket?D=FDA-2016-P-0645

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, June 07, 2016.

> *FDA should use evidence-based science to approve abuse-deterrent labeling.*

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, June 08, 2016.

> *The root cause of the opioid epidemic is the availability of extended-release long-acting opioid products such as OxyContin.*

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, August 04, 2016.

> *There is no scientific, medical, or legal evidence to justify the approval of an extended-release opioid drug.*

Statements before the Joint Meeting of the AADPAC, DSaRM and PAC Advisory Committees, Open Public Hearing, September 16, 2016.

Pediatric studies should never be conducted using extended-release opioid analgesics.

Statements at the Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products, November 01, 2016.

FDA in-vitro testing for abuse-deterrent opioids is fatally flawed and has resulted in the misbranding of opioid products.

Citizen Petition from Pharmaceutical Manufacturing Research Services, Docket ID FDA-2017-P-1359, March 07, 2017.

Request FDA revoke approval of all extended-release (ER) opioids indicated for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate" and all supporting chronic use labeling.

https://www.regulations.gov/document?D=FDA-2017-P-1359-0001

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, March 14, 2017.

The design of human abuse potential studies is invalid and should not be required in the approval of any drug product.

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, April 05, 2017.

FDA & the Opioid Epidemic: Summary of Wrongs

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, July 26, 2017.

Opioid Chronic-Use Indication is Unlawful

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, June 26, 2018.
/ Public Comment to Docket FDA-2018-N-3467

OxyContin as the RLD – clean-up committee or cover-up committee?

Citizen Petition from Pharmaceutical Manufacturing Research Services, Docket ID FDA-2018-P-4338, November 13, 2018.

Request that the FDA refrain from approving any pending or future application for an opioid product submitted pursuant to section 505(b) or 505(j) of the FD&C Act with an indication or any other labeling that suggests that the product is appropriate for chronic use.

https://www.regulations.gov/docket?D=FDA-2018-P-4338

Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, November 14, 2017.
/ Public Comment to Docket FDA-2018-N-3467

Oxycodone being marketed as a single-entity analgesic has no historical basis for approval.

Statements before the Joint Meeting of the AADPAC Advisory Committee, Open Public Hearing, November 15, 2018.

Combination rule: each drug must have a contribution to the claimed effects.

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60 Minutes: The Label (Season 51, Episode 19), February 24, 2019.

A drug manufacturer denounces his own industry and explains to 60 Minutes how a label change by the FDA expanded the use of opioids.

https://www.cbsnews.com/news/opioid-epidemic-did-the-fda-ignite-the-crisis-60-minutes/

Public Comment on the FDA 09/10/2020 – 09/11/2020 Advisory Committee Meeting to discuss the results of required postmarketing studies that evaluated the effect of the reformulation of OXYCONTIN on abuse, misuse, and fatal and non-fatal overdose. / Statements before the Joint Meeting of the AADPAC and DSaRM Advisory Committees, Open Public Hearing, September 11, 2020.

Reformulated OxyContin's physicochemical properties fail to deter manipulation. No postmarketing results can be attributable to the abuse-deterrent properties of the drug formulation, since the drug formulation does not actually have abuse-deterrent properties. FDA's error in approving abuse-deterrent labeling on this drug is a critical lapse in judgement, not supported by substantial evidence as required by law.

https://www.regulations.gov/document?D=FDA-2020-N-0982-0002

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COURSE MATERIALS

Cannabis & the FDA

Cannabis Law PA

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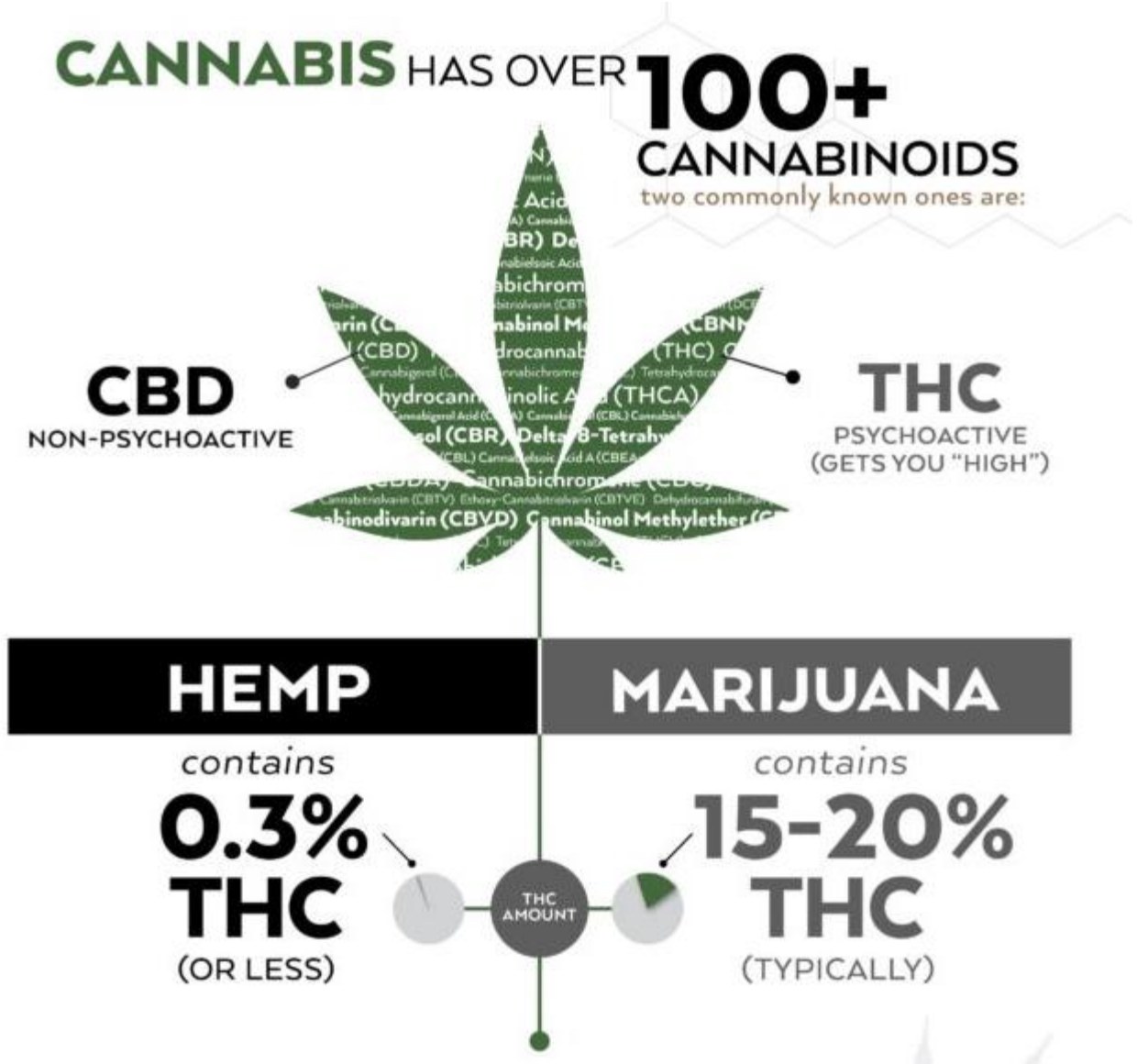
Melissa A. Chapaska, Esq.
machapaska@hmslegal.com

The Basics: What is Cannabis?



The Federal/State Conflict

Federal Controlled Substance Act (21 U.S.C. § 811)

Unlawful for any person "knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."

Marijuana is a "Schedule I" Controlled Substance

"No currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse."

Drug Scheduling Guide United States

Schedule I	Most potential for abuse and dependence No medicinal qualities	Heroin, LSD, Marijuana Ecstasy, Peyote
Schedule II	High potential for abuse and dependence Some medicinal qualities	Vicodin, Cocaine, Meth, OxyContin, Adderall
Schedule III	Moderate potential for abuse/dependence Acceptable medicinal qualities Doctor's prescription required	Tylenol with Codeine, Ketamine, Steroids, Testosterone
Schedule IV	Low potential for abuse and dependence Acceptable medicinal qualities Prescription required - fewer refill regulations	Xanax, Darvon, Valium, Ativan, Ambien, Tramadol
Schedule V	Lowest potential for abuse/dependence Acceptable medicinal qualities Prescription required - fewest refill regulations	Robitussin AC, Lomotil, Motofen, Lyrica

Source: United States Drug Enforcement Agency

The FDA and Marijuana

Current Policy

To date, the FDA has not approved a marketing application for cannabis for the treatment of any disease or condition.

The agency has, however, approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone).

The FDA has not approved any other cannabis, cannabis-derived, or cannabidiol (CBD) products currently available on the market.

The FDA and Hemp

U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical Quality Operations
IV
19701 Fairchild, Irvine, CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417

WARNING LETTER

VIA SIGNATURE CONFIRMED DELIVERY

October 31, 2017

Joel Stanley, CEO
Stanley Brothers Social Enterprises, LLC
d/b/a CW Botanicals
d/b/a CW Hemp
3515 N. Chestnut Street
Colorado Springs, CO 80907

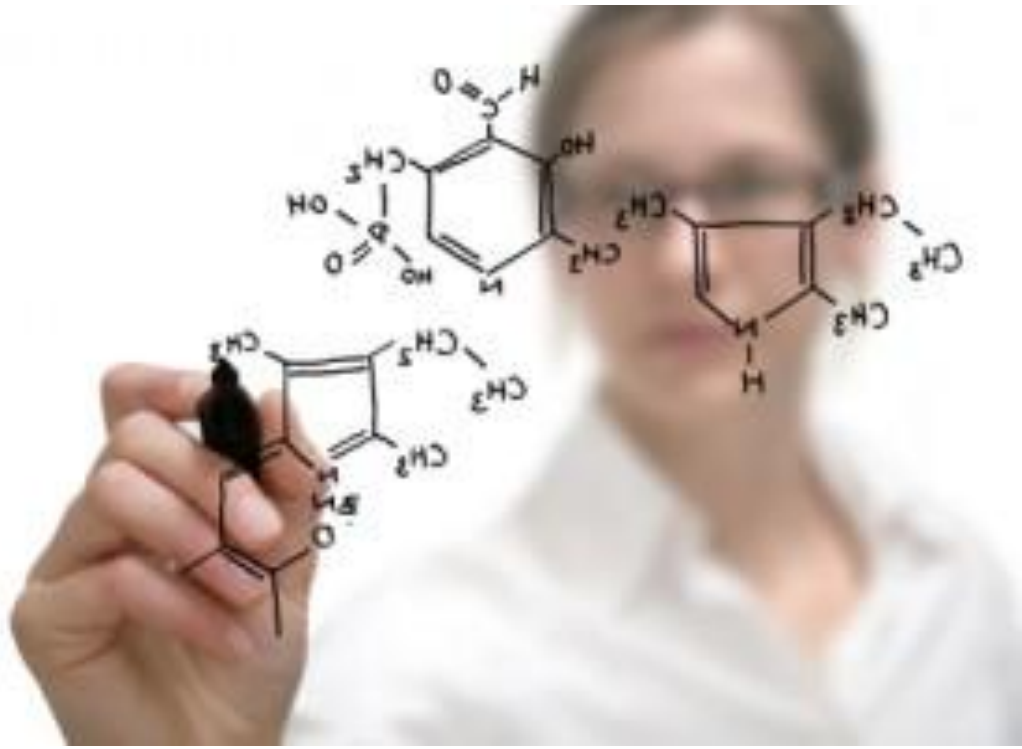
Dear Mr. Stanley:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.cwbotanicals.com (redirects to www.cwhemp.com) in August 2017 and has determined that you take orders there for the products "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," "Everyday Advanced Dietary Supplement" and "Charlotte's Web Gel Pen," which you promote as products containing cannabinoids, including cannabidiol (CBD). We have also reviewed your website at the internet address www.theroc.us, and your social media websites at www.facebook.com/CWHempOfficial and www.twitter.com/CWHemp; these websites direct consumers to your website, www.cwhemp.com, to purchase your products. The claims on your websites establish that the products are drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)] because they are 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. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

The FDA's Role in Marijuana Research

IND or INAD application to the appropriate CDER divisions or other center offices depending on the therapeutic indication or population.

Based on the results obtained in studies conducted at the IND or INAD stage, sponsors may submit a marketing application for formal approval of the drug.



Thank You!

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Course Materials – Judge Capuzzi

https://drive.google.com/file/d/10yGrko8tCGECCPvez32TmVxME3YjY5ly/view?invite=CMCqyagI&ts=5f7b1eeb

The FDA and Pet Products

Jessica Sleater

What type of meat cannot be used in pet food?

1. Non-USDA inspected meat
2. Roadkill
3. Animals that died in the field
4. Animals that have been euthanized

Answer:

4. Animals that have been euthanized based on FDA discretionary enforcement

What types of drugs can be used on animals?

1. Human Drugs
2. Drugs formulated for animals
3. Pesticides
4. All of the above

Answer:

4. All of the above

Overview of Federal Regulation of Pet Products

Food Drug Cosmetics Act (FDCA)

1. Law same for human and animal food and drugs

2. Different in application and enforcement

Food for Animals

A. FDA regulates “animal feed”

B. USDA regulates animal products for human consumption that it deems “edible”

C. States – Department of Agriculture
    1. License feed manufacturers and slaughter houses
    2. Conduct inspections of facilities
    3. Check labels for “guaranteed analysis” and proper weight

D. Association of American Feed Control Officials (AAFCO)

Non-regulatory organization that develops pet food definitions

Drugs for Animals

A. Treat medical condition

B. Prescription pet food

C. Flea and tick products/pesticides (can also fall under EPA and states)

FDA Approach to Regulation of Pet Products

A. Can be low-priority based on limited resources of agency focused on humans first

B. Reactive rather than proactive based on “news” of adverse events reported by pet owners and vets

C. FDA has stated that pet food manufacturers are responsible for taking appropriate steps to ensure that the food they produce is safe for consumption and properly labeled

Food Drug and Cosmetics Act

21 U.S.C. § 342(a)(1), a "food," which includes human and pet food, is considered adulterated if it contains a poisonous or deleterious substance; is contaminated by insanitary conditions; or is sourced from an animal that did not die by slaughter. Food may also be deemed adulterated if under § 342(b) it is substituted.

21 U.S.C. § 343(b), a food is deemed misbranded if it is offered for sale under the name of another food.

What can the FDA do?

1. Public warning
2. Warning Letter to company
3. Recall
4. Enforcement refer to DOJ/US Attorney for criminal charges or injunction

Hot Topics in Pet Food

1. **Pentobarbital**

- Drug used to euthanize animals
- 1990s: vets notice losing effectiveness; no FDA action after testing confirmed it was in some pet food
- 2016-18: found in pet food after reports of adverse events from pet owners; FDA ordered recalls and issued Warning Letters; consumer class actions lawsuits

2. Melamine

- 2007 pet foods imported from China contained added protein like a plastic caused sickness and death of pets
- FDA ordered recalls of over 150 different brands and consumer class actions
- Criminal charges against supplier

3. Jerky Treats

- 2007-13 treats imported from China lead to sickness and death of many pets
- FDA issued public warning but couldn’t determine cause
- NY testing found different drugs present
- Some retailers and manufacturers pulled products
- Consumer class actions

4. Substitution of Ingredients

- Purina sued Blue Buffalo falsely stating its pet food did not contain “meat byproducts”
- Consumer class action
- US Attorney criminal charges against supplier for introducing adulterated food (byproduct) falsely sold as non-byproduct
- Rare cases FDA tests (usually prompted by third party) and issues Warning Letter

5. Toxic Metals and Pesticides

- Recent testing revealed high levels of heavy metals and some pesticides in pet foods
- Consumer cases
- FDA no action because no regulation of this in pet food or testing to show it is harmful

Drugs for Animals

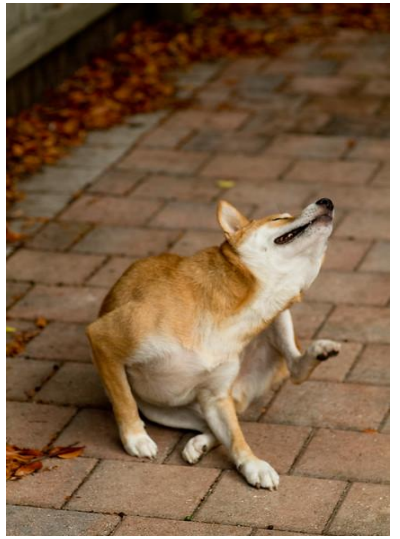
A. Specifically formulated for animals

- Subject to testing and pre-market approval by FDA
- Sampling often very small compared to human trials

B. Human drugs

- Not always know side effects on pets (different size and body chemistry)

Hot Topics in Animal Drugs



1. **<u>Pesticides</u>**

- Can be prescribed by vets
- New versions topical or chewable absorbed into animals' blood cells that kill insects when they bite animal
- FDA and EPA issued public warnings of adverse reactions to pets and required disclosure by manufacturers of health risks including recently of neurological ones relating to new products
- Consumer class actions

2. Prescription Pet Food

- FDA not pre-approve like “drug”
- some require prescription to purchase
- Can be used to “treat” health condition like allergies, urinary tract infections
- Consumer class actions challenging misrepresentation that they are “prescription” pet foods; recently upheld claims in 9th and 7th Circuits

Questions?

Acknowledgements

- YOU
- Delaware Law School Dean Rod Smolla and Assoc. Dean Alicia Kelly
- Delaware County Bar Assoc. President William (Bill) Baldwin and Nancy Ward, Assist. Dir.
- CLE Coordinator Carol Perrupato
- Alumni Official Judith McLaughlin
- Technical Head Dave Vallee
- 60 Minutes Assoc. Producer Sam Hornblower

Food and Drug Law Association Board

Jared Becker
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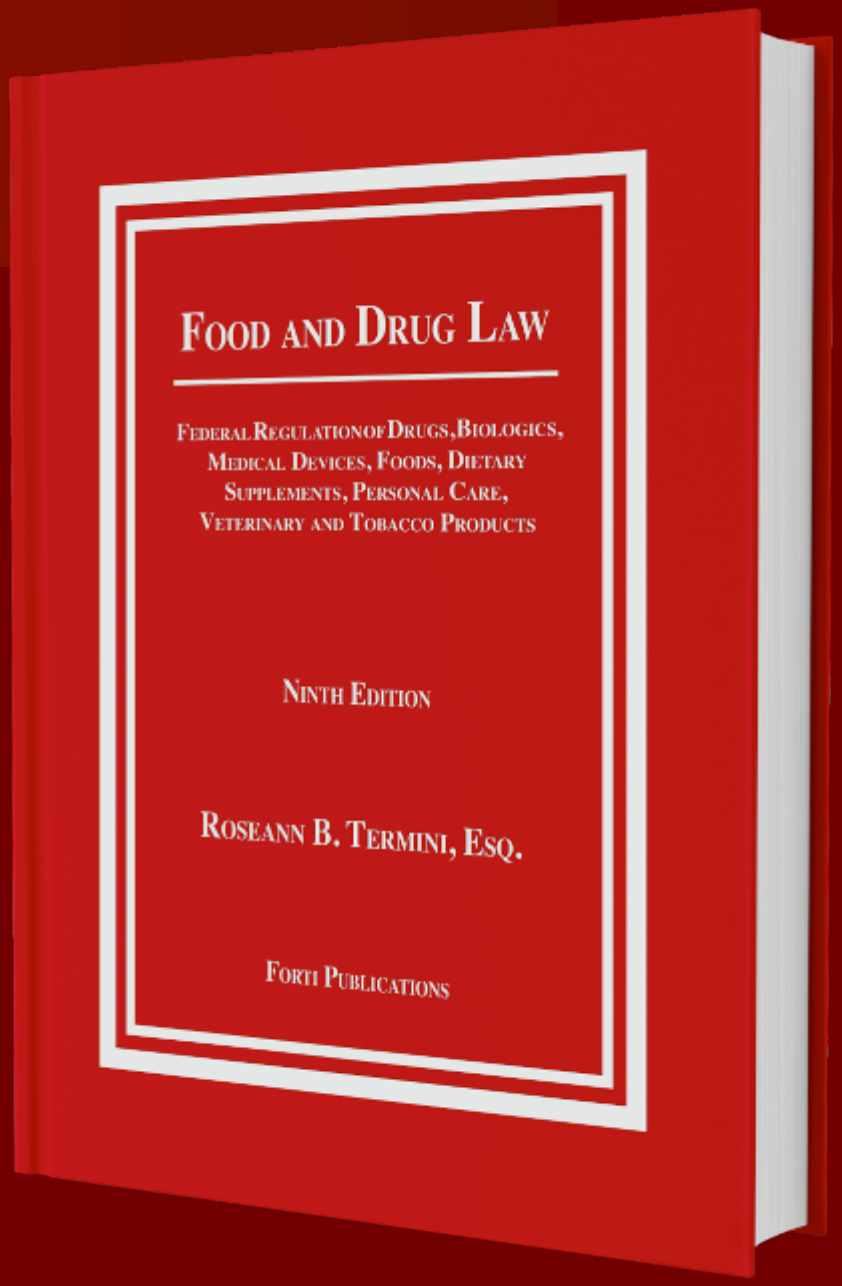
Haley Kubal



www.fortipublications.com

COVID-19, Right-to-Try, Unsafe Pet Products, Opioids, CBD, E-Cigarettes, Ethics ….

Roseann B. Termini

New Bottle Same Wine?

Roseann B. Termini

Rules of Professional Conduct

Key Focus

- Communication
- Competence
- Diligence
- Expediting Litigation

Zealous Advocacy

PA Rules of Professional Conduct

- Preamble
- Rule 1.3 Diligence
- Comment— Zeal in Advocacy
- *https://www.padisciplinaryboard.org/for-attorneys/rules/rule/3/#p-rule-960*

ABA Model Rules

Client Lawyer Relationship

Rule 1. 3 Diligence

- Comment—Zeal in Advocacy

Model Rules of Professional Conduct

Helpful Links

- ABA Model Rules https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/model_rules_of_professional_conduct_table_of_contents/
- PA https://www.flipsnack.com/ECB5E6B9E8C/parpc-09-14-2019.html

CODE OF CIVILITY

Coronavirus and COVID-19 Terminology

- SARS-CoV-2 Virus
- COVI=coronavirus
- D=Disease
- 19=year

c. Roseann B. Termini, Esq. Food and Drug Law: *Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products* www.fortipublications.com

Numbers

- Testing Emergency Use Authorizations EUA nearly 280 (Oct. 6, 2020) https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-october-9-2020
- Deaths over 200,000 (Oct. 9, 2020 CDC) https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm
- New Cases Over 57,000 U.S. (Oct. 10, 2020 Johns Hopkins)

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PREP ACT

- Public Readiness and Emergency Preparedness Act

- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas

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PREP ACT

- Public Health Emergency Declaration Notice Effective Feb. 4, 2020
- Needed for EUA under FDCA sec. 564
- Immunity from liability except willful misconduct

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Early on Confusion and Fake Cures

- Ex. Abbott Test for COVID-19 False Negatives (May 2020)
- Supplements – Colloidal Silver- Injunction Granted (May 2020)
- Herbs- Griffo Botanical and Prairie Dawn Herbs (Oct. 2020) (FTC and FDA)

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Medical Devices

- PPE- Personal Protective Equipment
- Ex. Goggles, Gowns, Respirators
- Are 3D Products same? Ask- Barrier
- https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic

COVID-19 CDC Confusion

- Does CDC recommend Testing?
- Testing Guidelines
- Contact and No Symptoms
- CDC Foundation Congressional Authorization 1992 Nonprofit

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Politics

- *Sex, Politics, and Lessons Learned from Plan B: A Review of the FDA's Actions and Future Direction*, Oklahoma L. Rev. Vol. 36, No. 2 (2011).

- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1988526

The 7 Former Commissioners

- *Robert Califf, Scott Gottlieb, Margaret Hamburg, Jane Henney, David Kessler, Mark McClellan and Andy von Eschenbach*
- *Urged Science Base*
- *Political Interference*
- *Public trust is paramount*

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COVID-19

- Researchers and Bioethicists Letter
- Rigorous Safety ex. follow
- https://bit.ly/2SpXWmN

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Trials Halted

- J&J
- Inovio

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COVID-19 France Lesson

- Paris Storefront Windows
- Regions

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COVID-19 Sweden Lessons

- Personal Responsibility—Voluntary actions vs.
- Government Imposed Rules
- Reason- Trust

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COVID-19 Lessons Learned South Korea

- Prepared based on past- 2015 MERS
- Patient #31
- Church 1,000
- Buffet

COVID-19 Lessons Learned South Korea

- Aggressive Mass Testing- Drive Through
- Strong Economy
- Quarantine
- Corporate Coordination
- Ex. Samsung Turned Dorms

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Autonomy
Right to request

- Right-to-Try State vs. Federal Legislation vs. Federal Compassionate Use
- States Right-to-Try impetus for Federal "streamlined" process and Federal Rt.-to-Try Law (2018).
- *Individual Patient Expanded Access Applications* - Form FDA 3926 (June 2016)

COVID-19 Perspective

- "As we continue to address Covid-19, it's important to reflect on what we've learned to better prepare ourselves for current and future epidemics."
- Jeffrey Shuren, M.D., J.D., Dir. Center for Devices and Radiological Health and Timothy Stenzel, M.D., Ph.D.
- https://www.nejm.org/doi/full/10.1056/NEJMp2023830

COVID-19 Pandemic Crisis Solution

- Trust and Confidence that FDA will use science-based assessments

Tobacco Products Regulation

Landmark Law

Signed into law: June 22, 2009

Family Smoking Prevention and Tobacco Control Act

What Does this Law Do?

- The FSPTCA granted the FDA new authority to regulate tobacco products to protect *public health.*

Who Created the Hawaiian Punch Mascot and the Kool-Aid Man?

Big Tobacco

- Hawaiian Punch- 1960s R.J. Reynolds
- Punchy
- Kool-Aid-Philip Morris – applied same marketing as R.J. R. ex. Direct to children—colors, flavors and characters

What about Tobacco and Youth?

- Strategies
- Minimum Age now 21
- FDA Continued Focus-Youth

Deeming Regulations Why and How Could this Happen

- **E-Cigarettes and Other Tobacco Products ex. Cigars**
- **Rulemaking 2016**
- **1996 Regs Comported 1st Amendment Principles**

Cigarillos

- Fruit Punch
- Brownie
- Mint Chocolate Chip
- Action- States and Local Municipalities
- 21 USC 387p: Preservation of State and local authority


5 CIGARS FOR 99¢
HI-FI CIGARILLOS
Fruit Punch
GUARANTEED FRESH
4K's
COOL MINT
5 CIGARS FOR 99¢
HI-FI CIGARILLOS
White Grape
4 CIGARS FOR 99¢
4K's
MINT CHOCOLATE CHIP
4 CIGARS FOR 99¢
4K's
GRAPE
5 CIGARS FOR 99¢
HI-FI CIGARILLOS
Watermelon
4 CIGARS FOR 99¢
4K's
FRENCH VANILLA
4 CIGARS FOR 99¢
4K's
5 CIGARS FOR 99¢
HI-FI CIGARILLOS
Fruit Punch
GUARANTEED FRESH

- Lawsuit— Local Ordinances
- TG Brands, Swisher and Swedish Match
- Ex. Phila. https://www.publichealthlawcenter.org/content/cigar-association-america-et-al-v-city-philadelphia-et-al-2020

Graphic Warnings

- The *American Academy of Pediatrics et al. v. United States Food and Drug Administration,* 1:16-cv-11985, (D. C. Mass. 2016).

Graphic Warnings

- Court ordered the FDA to issue long overdue revamped warnings on an expedited schedule since several years elapsed.

Graphic Warnings

- MEMORANDUM AND ORDER GRANTING INJUNCTIVE RELIEF (March 5, 2019)
- Proposed Rule submitted for Publication in the Federal Register by August 15, 2019
- Final Rule submitted for Publication in the Federal Register by March 15, 2020.

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Graphic Warnings Litigation

- https://www.tobaccocontrollaws.org/files/live/litigation/2631/US_American%20Academy%20of%20Pediatrics.pdf

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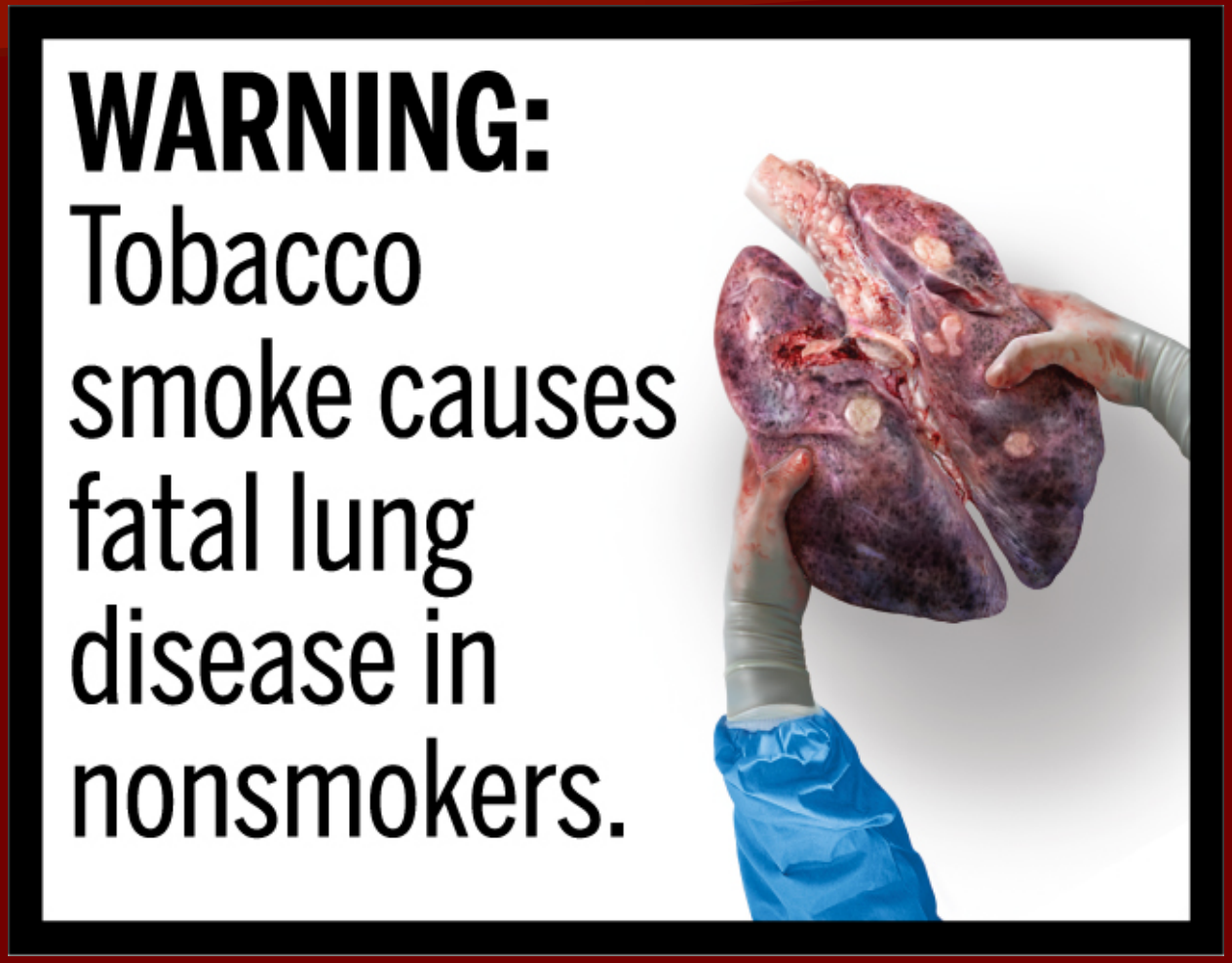
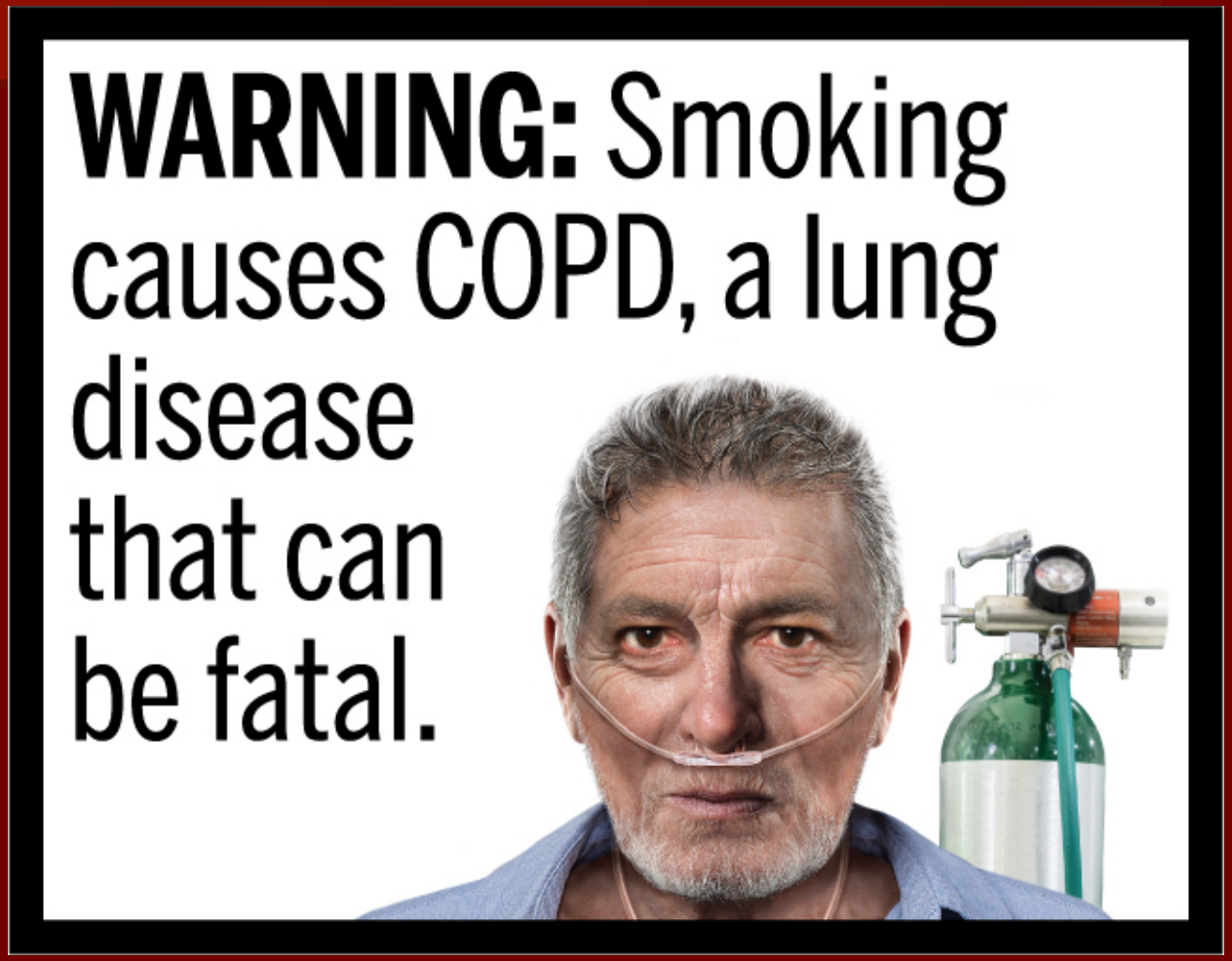
Graphic Warning Ex.



Health Warnings

- U.S. Food & Drug Admin., Required Cigarette Health Warnings, 2020, https://www.fda.gov/media/136157/download [https://perma.cc/2SRB-LYHD].


WARNING: Smoking causes COPD, a lung disease that can be fatal.

Lawsuit

- R.J. Reynolds and other tobacco companies concerning the issuance of the graphic warnings, Compl., *R.J. Reynolds Tobacco Company et al. v. U.S. Food and Drug Administration et al.*, No 6:20-cv-00176 (Dist. Ct. E. D. Tex., Tyler Div.).

The Numbers E-Cigarettes Youth Vaping

E-Cigarettes Vaping

- 3.6 million in 2017 to
- 4.9 million in 2018 to
- 5.8 million in 2019

Guidance Issued 2020

- Flavor Ban Does Not Apply to Tank Vaping Systems and Disposables
- Words of Wisdom- Read the fine line and footnotes.

Guidance Document

- Food & Drug Admin, Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization; Guidance for Industry (2020), https://www.fda.gov/media/133880/download [https://perma.cc/UG8G-86R7]

A Look Back at the Evolution of the Family Smoking Prevention and Tobacco Control Act and The Present-Day Impact on "Overlooked and Belated Issues"—Electronic Nicotine Delivery Systems (ENDS) and the Youth Epidemic, Menthol, Corrective Statements and Cigarette Labeling Graphic Health Warnings

- *Indiana Health Law Review, 2020.*https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3311583

Veterinary Products

Civil Lawsuits Veterinary Products

Who is the Gatekeeper?

Theory of Liability—ex. Consumer Protection Statutes

Civil Lawsuits Veterinary Products

- **Rx Pet Food**
- **Flea and Tick Rx Product Pentobarbital**

Purple Leash Project Red Rover and Purina

- Domestic Violence Awareness Month
- THE NUMBERS
- Nearly 50% Delay in Leaving Abusive Environment
- 1 in 3 women
- 1 in 4 men
- https://safeplaceforpets.org

OPIOID EPIDEMIC

Opioid Epidemic

- *50 Years Post-Controlled Substances Act: The War on Drugs Rages on with Opioids at the Forefront,* Ohio N.Law Rev. (co-authored), Vol. 46, Issue 1, Lead (2020).
- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3432531

Opioid Crisis

- President Trump Public Health Emergency
- All Encompassing
- Drugs, Addiction and Sex Trafficking

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Opioid Crisis
Executive Liability

- ***Purdue Pharma Revisited-***
- ***Key Element- how promoted***

Opioid Crisis

- Health Care Providers—Dentists- ages 10-19, Physicians, Insurers, Drug Companies, Hospitals, Distributors, Wholesalers, Nurses, Patients, and Victims ex. Infants

Opioid Crisis

- Gateway to Addiction
- Heroin
- Pandemic

Confusion and Cure All

CBD, Hemp, Medical Marijuana

Farm Bill

- On December 20, 2018, President Donald Trump Agricultural Improvement Act of 2018
- Commonly known as " 2018 Farm Bill"

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Classification and Confusion

- CANNABIS- family of plants
- HEMP vs. MARIJUANA
- Level of THC chemical compound induces psychoactive effects

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Cosmetic Safety

Makeover Needed

Medical Devices 510(k) Overhaul

This Is Not 1976 Anymore — Moving Forward in Medical Device Safety and the 510(K) Clearance Process Under the United States Federal Food, Drug, and Cosmetic Act

- Quinnipiac Health Law Journal (2020)
- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3593578

Dietary Supplements DSHEA Overhaul Needed

- 25 Years Later
- Proliferation in the marketplace
- How Regulated

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Dietary Supplements

A Look Back at DSHEA—Over 25 Years Later the Dangers of a Reactionary Approach to Dietary Supplement Regulation, Quinnipiac Health Law Journal, Vol. 22 Issue 2, Lead (2019)

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Looking Ahead

- FDA Oversight-Increased Self-Treatment
- Cyber Security Concerns
- Resources
- FDA Communication

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Final Commentary

- New Bottle New Wine-COVID-19
- Overdue Opioids
- Overdue E-Cigarettes

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Remember

- Mission of FDA
- Public Protection

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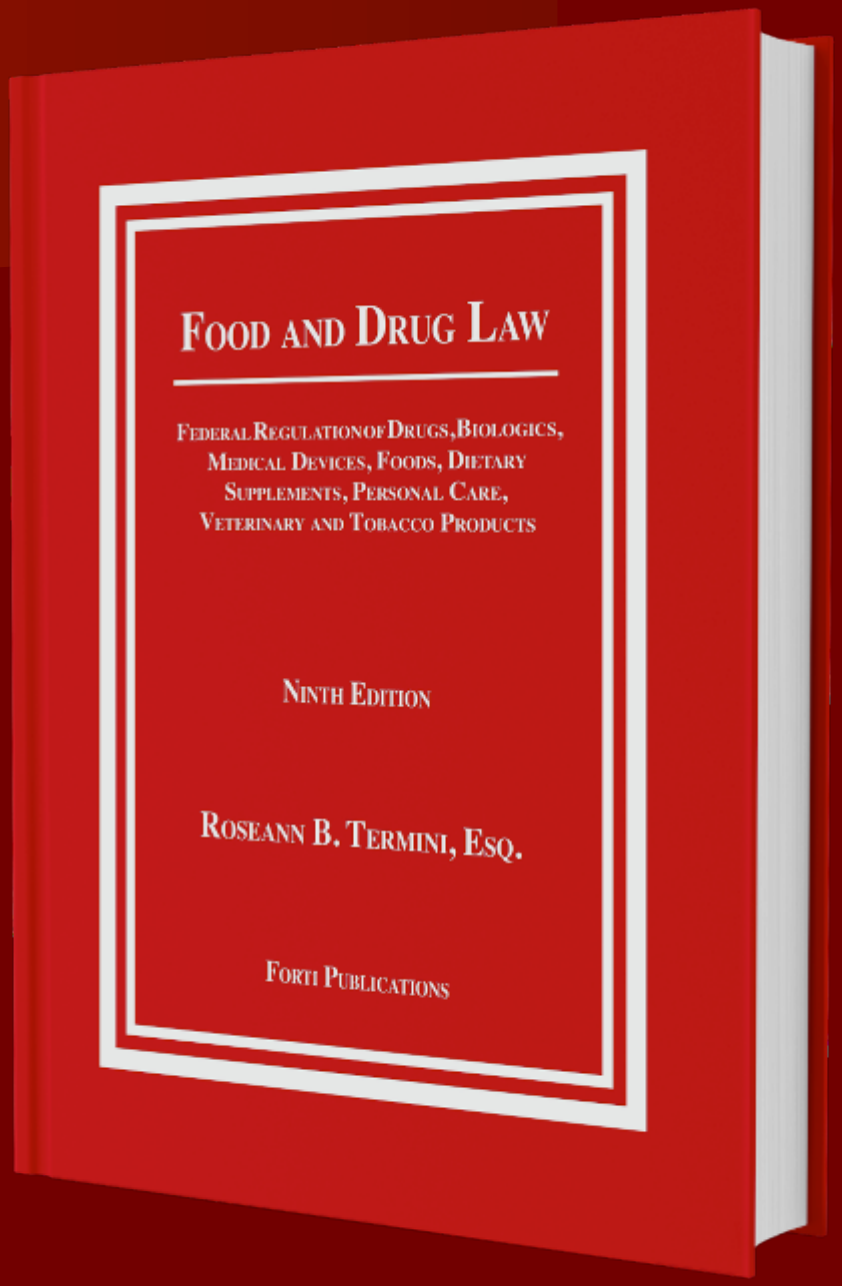
Save the Date March 24, 2021



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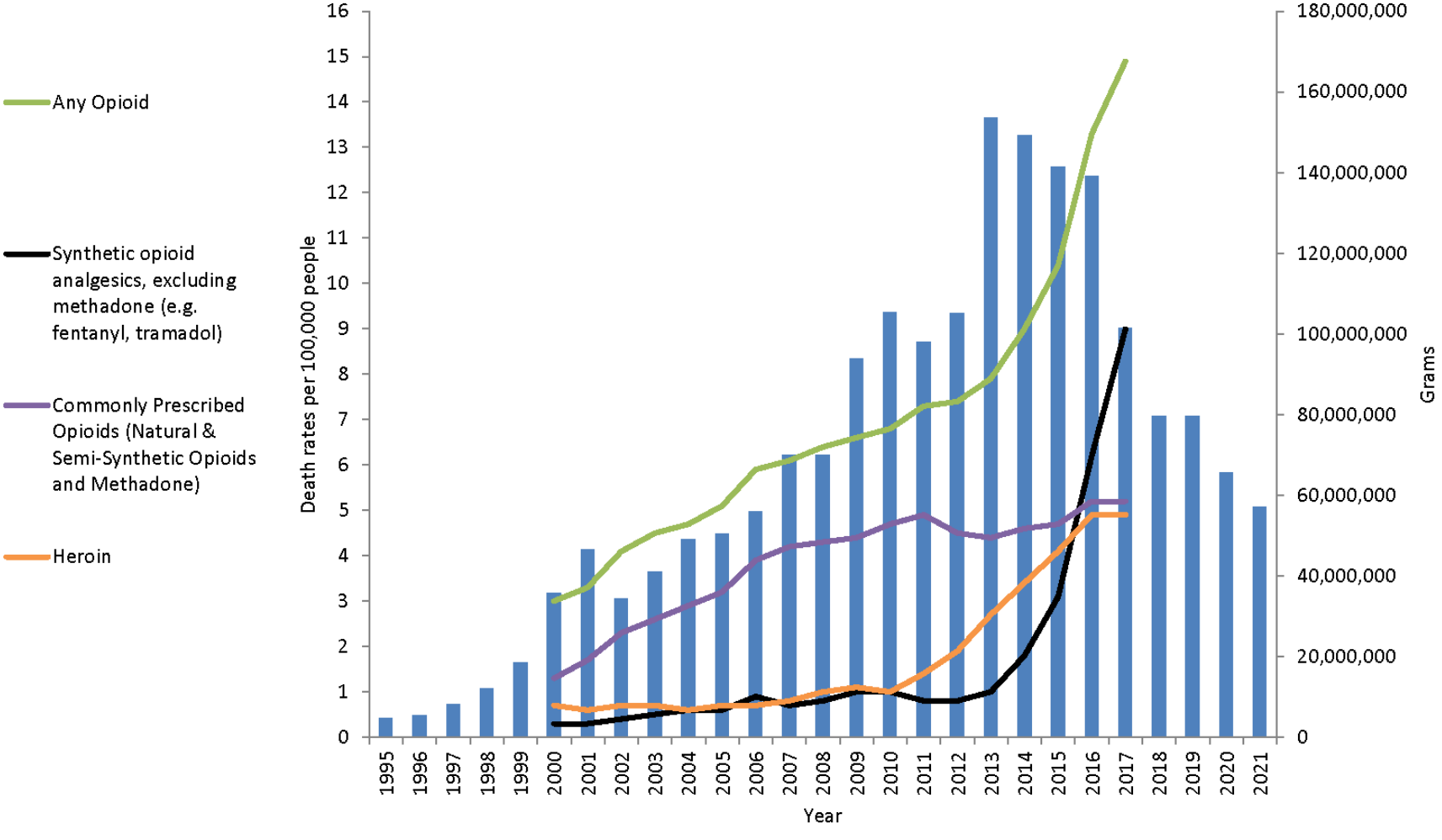
- www.linkedin.com/in/roseanntermini/

Edwin Thompson
President
PMRS, Inc.

October 21st, 2020

Overdose Death Rates Involving Opioids, by Type, Compared to Aggregate Production Quota of Oxycodone, in Grams, United States, 1995-2021



CDC's Dr. Thomas Frieden & Dr. Debra Houry:

- "Beginning in the 1990s, efforts to improve treatment of pain failed to adequately take into account opioids' addictiveness, low therapeutic ratio, and lack of documented effectiveness in the treatment of chronic pain."
- "Whereas the benefits of opioids for chronic pain remain uncertain, the risks of addiction and overdose are clear."
- "We know of no other medication routinely used for nonfatal conditions that kills patients so frequently."

https://www.nejm.org/doi/full/10.1056/nejmp1515917

Substantial Evidence

§314.125 Refusal to approve an NDA.

There is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in §314.126, that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling.

https://www.ecfr.gov/cgi-bin/text-idx?SID=2f91dff46a1fd998c9dffdea97187fc8&mc=true&node=sp21.5.314.d&rgn=div6#se21.5.314_1125

Pink Sheet
Informa Pharma Intelligence

CIBA-GEIGY's ACUTRIM MAY REMAIN ON THE MARKET WITHOUT APPROVED NDA, PRIOR TO FINAL MONOGRAPH; PHENYLPROPANOLAMINE IN OROS POSES NO SAFETY RISK, FDA SAYS

03 Dec 1984 | NEWS

by The Pink Sheet pinkeditor@informa.com

Executive Summary

FDA is formally dropping a regulatory action against Ciba-Geigy's Acutrim, the agency told the firm in a Nov. 26 letter. The OTC phenylpropanolamine weight control product may therefore remain on the market without an NDA, until publication of a final monograph on OTC weight control products. In a regulatory letter issued May

Pink Sheet
Informa Pharma Intelligence

PURDUE FREDERICK MS CONTIN SUSTAINED RELEASE MORPHINE SULFATE MARKETING WITHOUT FDA APPROVAL IS JUSTIFIED BY AGENCY'S ACUTRIM DECISION, FIRM SAYS

18 Feb 1985 | NEWS

by The Pink Sheet pinkeditor@informa.com

Executive Summary

Purdue Frederick is citing the regulatory status of Ciba-Geigy's Acutrim as a precedent for continued marketing of the sustained release morphine sulfate product MS Contin without an approved NDA. Acutrim is a "cogent example," Purdue Frederick said in a Jan. 28 letter to FDA, of "other controlled release products [that] have recently been permitted to be marketed without NDA approval where there is sound evidence to support the determination that the controlled release product successfully produces a relatively constant rate of release of the drug to avoid 'dumping.'" FDA said "that it would take no regulatory action against this new osmotic release oral system for phenylpropanolamine, because the data showed it did not dump and was a successful controlled-release product," Purdue Frederick continues. The firm's letter was in response to a Jan. 14 FDA regulatory letter stating that the agency regards MS Contin to be a new drug and therefore should not remain on the market. FDA

memo

LAS
File
oxycontin
labeling

to: OxyContin™ Launch Team

from: LJ Lydia Johnson

dept: Marketing

subject: Launch Team Meeting 3/31/95 Minutes

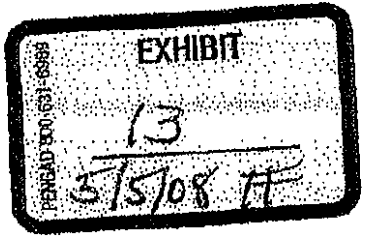
date: April 4, 1995

The first OxyContin Launch Team meeting was held on March 31, 1995. An introduction of the meeting was made by Mark Alfonso, followed by an overhead presentation by Mike Innaurato. A hard copy of the presentation is attached.

The OxyContin Launch Team's mission is to ensure a successful and timely launch of OxyContin. Mike Innaurato discussed the marketplace that OxyContin will enter, and how OxyContin will expand out of the cancer pain market. OxyContin will be launched in a 10, 20, and 40 mg tablet strength (80 and 160 mg tablet strength to follow). Tablets are small, color-coded and easy to swallow. Sample bottles of the three tablet strengths were passed around. OxyContin will be indicated for the relief of pain with the convenience of q12h dosing. OxyContin's primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain (musculoskeletal, injury and trauma). It was reinforced that we do not want to niche OxyContin just for cancer pain. OxyContin will be positioned into Step 2 of the W.H.O. Analgesic Stepladder (the opioid to start with), but we will also move OxyContin into Step 3 of the ladder (the opioid to stay with), since AB-rated generics will eventually affect MS CONTIN®. OxyContin's positioning statement is "all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing." The proposed features and benefits of OxyContin were listed. The convenience of q12h dosing was emphasized as the most important benefit.

In our Market Research efforts, focus groups, personal 1-on-1 interviews, and telephone interviews were conducted with more than 500 health care professionals. In our focus group findings, we learned that MS CONTIN® is the "gold standard" for cancer pain. Our creative concept testing showed the likelihood of OxyContin usage by physicians and nurses was 4.6 on a scale of 1 to 5, which is very favorable. Seventy six percent of those questioned would use OxyContin in opioid naive patients. The products that OxyContin will replace were listed in descending order: oxycodone combinations, hydrocodone combinations, codeine combinations, MS CONTIN, and Duragesic®.

The objectives were then mentioned and the professional target audiences and institutional target audiences were listed, showing there is a big non-cancer marketplace for OxyContin.



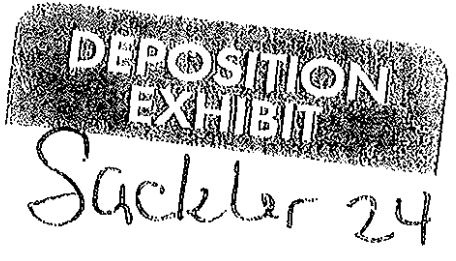
RECEIVED
APR 1 0 1995
L. A. STOREY

7024301502

CONFIDENTIAL-SUBJECT TO PROTECTIVE ORDER

PDD7024301502

PRODUCED BY PURDUE IN KISER V. PURDUE PHARMA COMPANY, ET AL.
(UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI, CIVIL ACTION NO. 3:07cv419-HTW-LRA)



CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL., CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

PDD9524706426

https://documents.latimes.com/oxycontin-launch-1995/

The classic model utilized in treatment of cancer pain is the World Health Organization (W.H.O.) Three Step Analgesic Ladder. The recommendations of the W.H.O. are:

Step 1: Use NSAIDs to treat mild pain, i.e., aspirin.

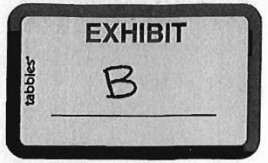
Step 2: Use weak opioids to treat moderate pain, i.e., codeine, oxycodone and hydrocodone combinations.

Step 3: Use strong opioids to treat severe pain, i.e., morphine.

OxyContin™

1996

BUDGET PLAN



- To generate 205,000 prescriptions in year 1, by capturing:
  - 15% of MS CONTIN Rxs written for cancer pain.
  - 10% of oxycodone combination Rxs written for cancer pain.
  - 10% of hydromorphone Rxs written for cancer pain.
  - 2.5% of Duragesic combination Rxs written for cancer pain.
- To convince health care professionals to replace 15% of MS CONTIN prescriptions (year 1) with OxyContin as their drug of choice for cancer pain.
- To establish OxyContin as the opioid of choice in Step 2 of the W.H.O. analgesic stepladder.

https://khn.org/news/purdue-and-the-oxycontin-files/

Changes to OxyContin Label

- **Addition of a Boxed Warning**

- **CLINICAL TRIALS section**
  - Restricted to the single adequate and well-controlled clinical trial.

controlled clinical trial.

- **INDICATIONS section revised to reflect the appropriate patient population.**

https://wayback.archive-it.org/7993/20170405203914/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM248776.pdf

MEDICAL OFFICER REVIEW (MOR)

Integrated Summary of Efficacy
Oxycodone Controlled Release

"OxyContin"

NDA #: 20-553
Sponsor: The Purdue Frederick Company
Type of Submission: NDA Submission
Date of Submission: 12/28/94
Date Received: 1/31/95
Date of Review: 2/2/95
Review Completed: 6/19/95
Review Time: 40 hours
Calender Time: 4 months
Reviewer: Curtis Wright, M.D.

CLINICAL STUDIES

Study Name	Indication	N	Comparison	Duration	PK/PD?
Controlled Trials					
OC91-0402A	CANCER	57/54	CR V. IR	5 DAY + / -	
OC91-0402B	CANCER	81/83	CR V. IR	5 DAY + / -	
OC93-0202	CANCER	50	CR V. IR	7 DAY X-O	PK/PD
OC92-1102	OA	44/44/45	10,20 CR V PLC	14 DAY	PK/PD
OC92-1201	LOW BACK	57	CR V. IR	7 DAY X/O	PK/PD
OC88-1105	POSTOP	30/30/30 30/31/31	10,20,30 CR IR. PLC. PCT	SINGLE DOSE	none

https://www.regulations.gov/contentStreamer?documentId=FDA-2018-N-1797-0011&attachmentNumber=6&contentType=pdf

Pain Intensity by Study Week (Evaluable Patients)

WEEK 1	N	Mean	Std. Dev.	Std. Error
Placebo	38	2.047	.614	.100
CR Oxycodone 10	37	2.023	.519	.085
CR Oxycodone 20	34	* 1.595	.706	.121

WEEK 2	N	Mean	Std. Dev.	Std. Error
Placebo	38	2.087	.708	.115
CR Oxycodone 10	37	1.905	.764	.126
CR Oxycodone 20	34	* 1.614	.761	.131

* "p" < 0.05

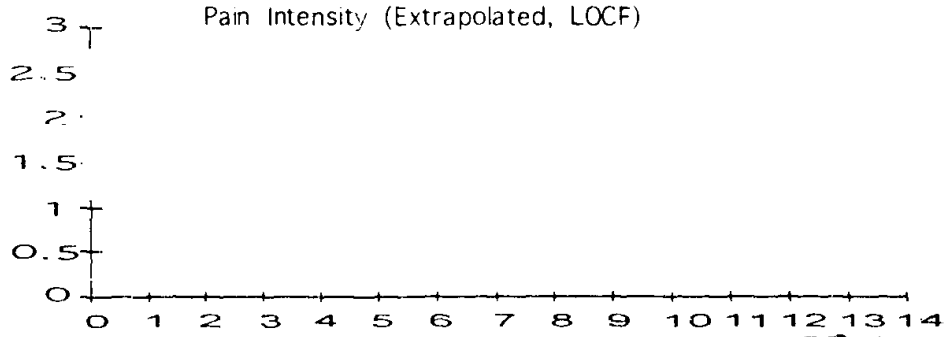
Conclusion

This double-blind, parallel-group, dose-response study provides substantial evidence of the short-term analgesic efficacy of CR Oxycodone (20 mg) in patients in this chronic pain model.

Study 1201- A Cross-Over Study of IR & CR Oxycodone in a Chronic Low Back Pain Model

This was a multi-center, double-blind, randomized, repeated dose, two-period crossover study in patients with stable, chronic low back pain. Patients, initially, entered an open-label titration period and were randomly assigned to receive either open-label controlled-release (q12h) or immediate-release (qid) oxycodone to achieve pain control (titration). Following titration, patients were randomly re-assigned to a double-blind treatment sequence of either controlled-release oxycodone to immediate-release oxycodone (CR => IR) or the reverse (IR => CR). After completion of Period 1, patients received the alternate treatment.

One blood sample was drawn at trough at the end of titration (double-blind baseline). Blood samples were then drawn after 3-5 days on each treatment at trough, 1, 3 & five hours post dose.



Discussion

Oxycodone 20 mg separated from placebo within a week with an effect size of about 0.4/0.6 or 2/3 SD. The 10 mg was not effective, but provided information as a half-dose dose control. This data is not adequate by itself to support an OA indication, but is a very helpful trial in a non-oncologic chronic pain model.

* "p" < 0.05 CR 20 v. Placebo

Discussion

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PK/PD

The pharmacokinetic analysis of the plasma oxycodone concentrations revealed:
(1) a dose-proportional relationship
(2) a consistent 0 to 3 hour relationship

Pharmacodynamics

A single-dose, double-blind, placebo- and dose-controlled study was conducted using OxyContin® (10, 20, and 30 mg) in an analgesic pain model involving 182 patients with moderate to severe pain. Twenty and 30 mg of OxyContin® were superior in reducing pain compared with placebo, and this difference was statistically significant. The onset of analgesic action with OxyContin® occurred within 1 hour in most patients following oral administration.

CLINICAL TRIALS

In this study, 20 mg OxyContin® q12h but not 10 mg OxyContin® q12h decreased pain compared with placebo, and this difference was statistically significant. pain, who were judged as having inadequate pain control with their current therapy. In this study, 20 mg OxyContin® q12h but not 10 mg OxyContin® q12h decreased pain compared with placebo, and this difference was statistically significant.

INDICATIONS AND USAGE

OxyContin® tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/20553s22lbl.pdf

Dr. Wilson Compton, NEJM 2016 –

"Among persons who began their opioid use in the 1960s, more than 80% reported that their first opioid was heroin; conversely, in the 2000s, a total of 75% of users initiated opioid use with prescription opioids."

"[F]rom 2008 through 2010 77.4% [of abusers of both prescription opioid and heroin] reported using prescription opioids before initiating heroin use."

https://www.nejm.org/doi/full/10.1056/NEJMra1508490

Conclusion

- **The FDA has illegally approved extended-release opioid drugs for the treatment of chronic pain.**
- **Neither the executive branch (FDA, CDC, DEA), nor Congress is interested in meaningful action to stop the epidemic.**
- **The solution to stopping the opioid epidemic lies within the legal community.**

Questions may be sent to: ethompson@pmrsinc.com