FIRST AMENDMENT & FOOD LAW: NEW DEVELOPMENTS

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in the Public Interest

Compelled Warnings

Compelled Labeling

Voluntary Claims

CAN WE SAY IT? MUST WE SAY IT?

COMPELLED WARNINGS – MUST WE?

- *ABA v. San Francisco*
- Passed in June 2015, the San Francisco Ordinance was limited to **large advertisements** such as billboards, bus signage, signage on structures, including in arenas and on walls. By its terms, the ordinance is not applicable to ads in magazines, newspapers, and electronic media, or to product labels. Warning must occupy at least **20%** of advertisement.

Status –

- ABA sought a preliminary injunction to block implementation. San Francisco prevailed before Judge Chen in the N.D.Cal.
- ABA prevailed initially in the 9th circuit (9/2017)
- SF's petition to be reheard en banc granted (1/2018) ("The three-judge panel disposition in these cases shall not be cited as precedent by or to any court of the Ninth Circuit.")
- 9th Circuit stayed proceedings pending the U.S. Supreme Court's determination in *Nat'l Inst. of Family & Life Advocates v. Becerra*, where California law required pregnancy centers to provide information about abortion (3/ 2018)

SF SSB WARNING

LEGAL STANDARD

Regulators can require a commercial actor to divulge information so long as it is "reasonably related to the State's interest in preventing deception of consumers."
Zauderer v. Office of Disciplinary Counsel,
471 U.S. 626, 651 (1985)

In essence, the compelled speech must be:

1. Factual and non-controversial ;
2. Not unduly burdensome; and
3. Reasonably related to state's interest.

IS IT FACTUAL AND NON-CONTROVERSIAL?

- **FDA**: "***[S]trong and consistent evidence***" shows an ***association between sugar drinks and excess body weight*** in children and adults. 81 Fed. Reg. at 33,803 (emphasis added) (citing the findings of the 2015 DGAC).

- **CDC**: "Frequently drinking sugar-sweetened beverages ***is associated with weight gain/obesity, type 2 diabetes, heart disease, kidney diseases, non-alcoholic liver disease, tooth decay and cavities, and gout, a type of arthritis***. ***Limiting the amount of SSB intake can help individuals maintain a healthy weight*** and have a healthy diet." CDC, ***Get the Facts****: Sugar-Sweetened Beverages and Consumption* (last updated April 7, 2017) (emphasis added). *See also* CDC, *Beverage Consumption Among High School Students—United States, 2010* (June 17, 2011), https://goo.gl/aAD5ba (***sugar drinks are a "factor contributing to the prevalence of obesity among adolescents*** in the United States" (emphasis added)).

- **World Health Organization** ("WHO"): "Current evidence suggests that increasing consumption of sugar-sweetened beverages is associated with overweight and obesity in children. Therefore, ***reducing consumption of sugar-sweetened beverages would also reduce the risk of childhood overweight and obesity***." WHO, *Reducing Consumption of Sugar-sweetened Beverages to Reduce the Risk of Childhood Overweight and Obesity*, https://goo.gl/5pDE9K (last visited Feb. 8, 2018) (emphasis added). *See also* WHO, *Reducing Consumption of Sugar-sweetened Beverages to Reduce the Risk of Unhealthy Weight Gain in Adults*, https://goo.gl/Pn46gt (last visited Feb. 8, 2018) (same, for adults).

- **2015 DGAC**: "***Strong and consistent evidence shows that intake of added sugars from food and/or sugar sweetened beverages are associated with excess body weight in children and adults***"; "***[s]trong evidence*** shows that higher consumption of added sugars, ***especially sugar sweetened beverages***, increases the risk of ***type 2 diabetes*** among adults and this relationship is not fully explained by body weight." U.S. Dep't of Agric. & U.S. Dep't of Health & Human Serv., Scientific Report of the 2015 DGAC, pt. D, ch. 6, p. 20 (2015) (emphasis added). *See also id.* (recommending that added sugar not exceed 10% of total caloric intake).

- **American Medical Association** ("AMA"): AMA, the largest association of physicians and medical students in the United States, recently adopted a ***resolution supporting "warning labels to educate consumers on the health harms of SSBs***." AMA also backs a "***comprehensive approach targeting sugary drinks***," which includes policies to: encourage "hospitals and medical facilities to offer healthier beverages, such as water, unflavored milk, coffee and unsweetened tea, for purchase in place of SSBs"; request "outlets to display 'calorie counts for beverages in vending machines to be visible next to the price'"; encourage "physicians to suggest their patients '***replace SSBs with healthier beverage choices***, as recommended by professional society clinical guidelines'"; and encourage physicians to "work with 'local school districts to ***promote healthy beverage choices*** for students.'" Sara Berg, ***AMA Backs Comprehensive Approach Targeting Sugary Drinks***, AMA WIRE (June 14, 2017), https://goo.gl/tyAgGf (emphasis added).

- **Institute of Medicine** ("IOM"): "[R]esearchers have found ***strong associations between intake of sugar-sweetened beverages and weight gain***"; "***their link to obesity is stronger than that observed for any other food or beverage*** . . . ." IOM, Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation at ch. 6, p. 169 (2012), https://goo.gl/pZRas8 (emphasis added).

- **American Heart Association** ("AHA"): "***There is a robust body of evidence that SSB consumption is detrimental to health and has been associated with increased risk of CVD mortality, hypertension, liver lipogenesis, [type 2 diabetes], obesity, and kidney disease***." Linda Van Horn et al., *Recommended Dietary Pattern to Achieve Adherence to the American Heart Association/American College of Cardiology (AHA/ACC) Guidelines: A Scientific Statement from the American Heart Association*, 134 CIRCULATION e1, e8 (2016), https://goo.gl/rr9or6 (emphasis added). "Therefore, it is recommended that children and adolescents limit their intake of SSBs to 1 or fewer 8-oz beverages per week (Class I; Level of Evidence A)." Miriam B. Vos et al., *Added Sugars and Cardiovascular Disease Risk in Children: A Scientific Statement from the American Heart Association*, 135 CIRCULATION e1017, e1033 (2017), https://goo.gl/3So4H1.

- **American Public Health Association** ("APHA"): "***Consumption of [sugar] drinks is a significant contributor to the obesity epidemic and increases the risk of type 2 diabetes, heart disease, and dental decay***." APHA, *Taxes on Sugar-Sweetened Beverages* (Oct. 30, 2012), https://goo.gl/XGdrMZ (emphasis added).

- **American Diabetes Association** ("ADA"): "***The American Diabetes Association recommends that people should avoid intake of sugar-sweetened beverages to help prevent diabetes***." ADA, *Diabetes Myths* (last edited July 5, 2017), https://goo.gl/DUxU2u (emphasis added).

IS THAT CONTROVERSY REAL?

Be careful of relying on agenda-driven science.

Meta analyses increasingly indicate a strong bias toward the funder.

What does this mean for

public health?

A recent article by Dr. Schillinger published in PLOS examined 60 studies on the association between SSB consumption and obesity or diabetic outcomes, and found:

26 of 26 studies finding no association had funding ties to industry (100%);

whereas only 1 of 34 positive studies had such ties.

IS IT A BURDEN OR NOT A BURDEN?

CAMPAIGN FOR TOBACCO FREE KIDS WEIGHS IN AS AMICUS ON SIZE OF WARNING ABA V. SF (9TH CIR), ECF NO. 82

MUST WE WARN ON CARCINOGENICITY?

Claimed that requirement to label product as a carcinogen violates company's free speech rights if statement is not clearly true.

Lower court ruling temporarily blocks California from requiring labelling of products containing the herbicide glyphosate.

At issue: whether state could be forced to defend the scientific basis for listing chemicals under Proposition 65, and not adopt findings of any one "authoritative body" referenced in the law.

National Ass'n of Wheat Growers v. Zeiss, 2018 WL 1071168 (E.D. Cal. Feb. 26, 2018)

MUST WE CALL IT THAT?

South Mountain Creamery v. Gottlieb, Case No. 18 Civ. 738 (YK) (M.D. Pa. April 5, 2018)

Institute for Justice:

"Does the government have the power to override common sense and force American businesses to lie to their consumers? According to a First Amendment lawsuit that South Mountain Creamery and the Institute for Justice (IJ) filed today against the U.S. Food and Drug Administration (FDA) in federal court, the answer is: Absolutely not."

http://ij.org/case/fda-skim-milk/

CAN THE FDA DEFINE THE SOI?

- The standard of identity for milk requires vitamins A and D. Milk without fat may be named skim milk, if it is not nutritionally inferior. If nutritionally inferior, it must be labeled "imitation."
- South Mountain claims phrase "imitation skim milk" is: 1) misleading; 2) fails to advance any legitimate government interest; and 3) not tailored to any such interest.
- The11th Circuit recently held that a parallel state regulation violated the FA. Subsequently Florida agreed the milk could be labeled "PASTEURIZED SKIM MILK, VITAMINS A & D REMOVED WITH CREAM."
- *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017).

WE CAN SAY THIS IF WE WANT TO, RIGHT?

AG Investigations:

Exxon Mobil v. Schneiderman, 2018 WL 1605572 (SDNY March 29, 2018)*

→

First Amendment defense to subpoenas in consumer & securities fraud investigations for records on statements over time about climate change and/or reflecting internal understanding. Assert AGs trying to suppress Exxon's "contrary viewpoint."

→

Rejected:

"Exxon's allegations that the AGs are pursuing bad faith investigations in order to violate Exxon's constitutional rights are implausible and therefore must be dismissed for failure to state a claim."

Massachusetts state court found similarly.

WHAT MIGHT CONSUMERS DO IF WE SAY THAT?

A few of the statements at issue in *Lamar v. Coke & ABA*:

"There is no scientific evidence that connects sugary beverages to obesity." Coke Senior VP

"Coca-Cola is an excellent complement to the habits of a healthy life." Former Coke CEO

"Most of the focus in the popular media and the scientific press . . . blames . . . sugary drinks [for obesity] and there is really virtually no compelling evidence that that, in fact, is the cause." Coke-funded scientist.

"Recently we've seen some food activists allege that sugar-sweetened beverages 'cause' obesity, diabetes and a host of other adverse health conditions. Obviously they are hoping you never look at the science behind their claims. *Because it doesn't exist.*." ABA website

LAMAR V. COCA-COLA & ABA

DISTRICT OF COLUMBIA SUPERIOR COURT

ABA: "Permitting public dissemination of only one point of view on disputed scientific questions is anathema to the First Amendment."

Plaintiffs: "To receive First Amendment protection, commercial speech must at least not be misleading." *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557, 566 (1980)

VIEWPOINT DISCRIMINATION OR DECEPTIVE SPEECH?

FIRST AMENDMENT REVIEW

Commercial statements are entitled to no First Amendment protection if found to be deceptive or misleading. *E.g.*, ***Virginia State Bd.*** *of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 (1976) (noting that the First Amendment does not "prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely").

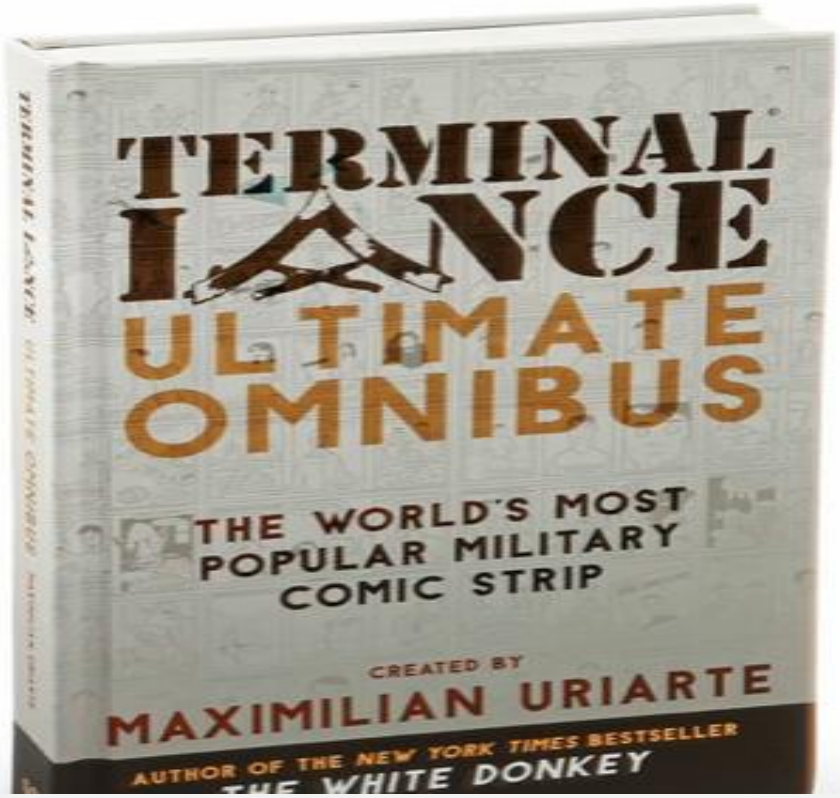
Holding that in order to receive First Amendment protection, commercial speech "at least must . . . not be misleading." ***Cent. Hudson*** *Gas & Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557, 566 (1980).

Commercial speech extends to a broad range of representations outside the "core notion" of commercial speech, including "material representations about the efficacy, safety, and quality of the advertiser's product, and other information asserted for the purpose of persuading the public to purchase the product." *U.S. v.* ***Philip Morris*** *U.S.A. Inc.*, 566 F.3d 1095, 1143 (D.C. Cir. 2009)

"[T]hose who seek to convey commercial messages will engage in the *most imaginative of exercises* to place themselves within the *safe haven of noncommercial speech*, while at the same time conveying their commercial message." ***Metromedia,*** *Inc. v. City of San Diego,* 453 U.S. 490, 540 (1981) (Brennan, J., concurring)

A NOTE OF HUMOR

"All of my stuff is organic, homegrown, no G.M.O., real lance corporal from the actual corps," he said.



Click here to watch how a "Terminal Lance" comic strip comes to life.

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First Amendment Updates – Drugs/Biologics

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Case Law Refresh

- *United States v Caronia* (2d Cir. 2012)
  - Criminal misbranding prosecution against pharmaceutical sales rep based on off-label promotional speech
  - Government cannot prosecute pharmaceutical manufacturers and their representatives under FDCA for truthful speech promoting the off-label use of an FDA-approved drug
    - "We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs"
- *Amarin Pharma, Inc. v. FDA* (S.D.N.Y 2015)
  - Court rejected FDA's attempt to limit *Caronia* to the facts
    - "Where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia,* cannot be the act upon which an action for misbranding is based."
    - Detailed analysis of statements and disclosures that would be truthful and non-misleading

PhRMA-BIO Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines With Health Care Professionals and Payers

Key Concepts

- Commitment to Science-based Communication
- Commitment to Provide Appropriate Context about Data
- Commitment to Accurate Representation of Data

Principles

- Commitment to Accurate, Science-Based Communications
- FDA-Approved Labeling is a Primary Source in Sharing Information with HCPs
- Companies Should Provide Scientific Substantiation if Shared Information is Not Contained in FDA-Approved Labeling
- Additional Science-Based Information from Sources Other than FDA-Approved Labeling Helps HCPs and Payers Make Informed Decisions for Patients
- Communications Should be Tailored to the Sophistication of the Intended Audience
- Science-Based Information About Alternative Uses of Medicines Can Improve Health Care Decision Making
- Communicating with Payers About New Medicines and New Uses of Approved Medicines Facilitates Patient Access Upon Approval
- Real-World Evidence Based on Patient Experience and Pharmacoeconomic Information Can Improve Understanding of Healthcare Outcomes and Costs
- Commitment to Share Information Published in Scientific or Medical Journals

2017 Draft Guidance, Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Q&A

- Draft Guidance
  - Communication of HCEI to payors regarding approved drugs (FDAMA 114)
  - Communications to payors about investigational drugs and devices
- PhRMA Comments on 2017 Draft Guidance
  - Underscored the public health need for payor access to truthful, non-misleading information about medical products
  - Requested clarity on scope of appropriate audience for FDAMA 114
  - Requested clarity on scope of communications that "relate to" an approved indication, consistent with FDAMA 114
  - Requested that FDA confirm that RWE can constitute CARSE
  - Recommended more flexibility in disclosures tailored to sophistication level of audience
  - Recommended that the draft guidance approach to wholly investigational products apply to unapproved uses of approved products

FDA Intended Use Rulemaking

- Sept. 2015 – FDA proposed to amend intended use rule
  - "The Agency does not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that such product was being prescribed or used by doctors for such use."
- Jan. 2017 – Final rule with new "totality of the evidence" prong for intended use
- Feb. 2017 – Delayed effective date of changes to intended use final rule
  - PhRMA/BIO/MIWG Petition for Stay and Reconsideration
    - New "totality of evidence" standard violated fair notice requirements under APA and is inconsistent with First Amendment
- Mar. 2017 – FDA further delays effective date of changes to intended use rule
- Jan. 2018 – FDA indefinitely delays effective date of changes to "allow further consideration of the substantive issues raised in . . . comments."
  - PhRMA Comments
    - Withdraw final rule and implement new policy aligned with PhRMA-BIO Principles
    - Reverting back to prior regulatory definition creates uncertainty and potentially chills beneficial communication

Pending FDA Action?

- Recent statements suggest FDA intends to finalize Payor Guidance
  - Rachel Sherman: "FDA is done. It is out of our hands. We think the industry will find [the final draft guidances] very useful." Remarks at BIO CEO & Investor Conference (Feb. 12, 2018)
  - Scott Gottlieb: "FDA will shortly be releasing a final guidance on communication of pharmaco-economic information between manufacturers and sophisticated intermediaries like PBMs and hospital-based pharmacy and therapeutics committees. Reliable scientific and economic information, including information that may not be in the FDA approved label, can support more flexible drug pricing and coverage agreements, including indication-based payments." Speech to Pharmaceutical Care Management Association (Apr. 19, 2018)

STAY TUNED!

Medical Device Pre-Approval Communications and the First Amendment

FDLI Annual Conference
May 4, 2018

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FDLI

Basic Rules for Development Stage Communication

- Thou Shall Not Discuss Beyond the Anticipated Approved Label
  - Whatever the company says now about its upcoming product will create an impression in the minds of the customers who may ultimately be asked to purchase that product.
  - If the company describes uses that do not ultimately get approved, the company will be creating an off-label promotion situation once the product is introduced into commercial distribution.

Courtesy of Brad Thompson, Epstein, Becker & Green

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Basic Rules for Development Stage Communication

- Thou Shall Tell the Truth
  - Both FDA and FTC would have difficulty proceeding against the company for statements made in advance of any product being placed in commercial distribution. (But other laws may still be relevant.)
  - However, once the opportunity to acquire the product exists, any prior statements would be evaluated for their truthfulness. Being truthful means, among other things, the statements are adequately supported by **valid scientific evidence** at the time they are made.

Courtesy of Brad Thompson, Epstein, Becker & Green

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Recent cases of interest

- *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011)
- *U.S. v. Caronia,* 703 F.3d 149 (2d Cir. 2012)
- *Amarin Pharma, Inc. v. FDA*, No. 15 Civ. 3588 (PAE), 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015)
- *U.S. v. Vascular Solutions, Inc.,* Case No. 5:14-cr-00926 (W.D. Tex.)
- *U.S. v. Facteau*, Case No. 1:15-cr-10076-ADB (D. Mass.)

FDLI

U.S. v. Vascular Solutions

- The Court rejected the defendants' First Amendment argument because the government stated it intended to prove the misbranding violation by only relying on conduct.
- The Court affirmed the prior case law that speech may serve as an overt act in a conspiracy case, stating that "[t]he Court . . . sees no First Amendment threat from this proposed use of speech."

FDLI

US v. Facteau Jury Charge

- **The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded.** Although you may not convict a Defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict, there must be a criminal act. **Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.** Dkt. No. 436 at 26-27.

FDLI

Where Do We Stand After *Facteau*?

- Advantage: Government
  - But, Motion for Acquittal still pending after 18 months
- Favorable instructions
- 30 day trial: $$$
- Multiple convictions, albeit misdemeanors
- Other potential consequences

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To off-label promote or not, that is the question

Benefits

- Sales and profits
- Innovative reputation?

Risks

- Damage to reputation
- Attorneys' fees
- Time-consuming litigation (civil and criminal)
- Fines
- Debarment
- Prison

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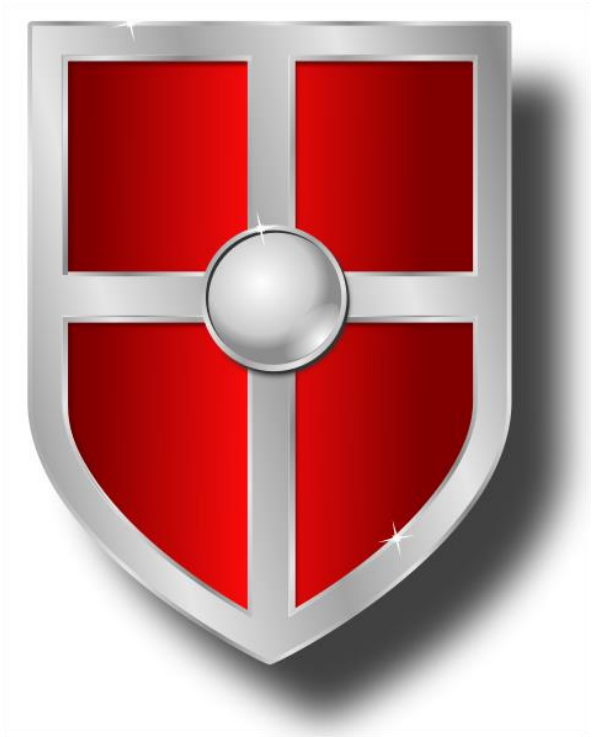
Proceed with caution…



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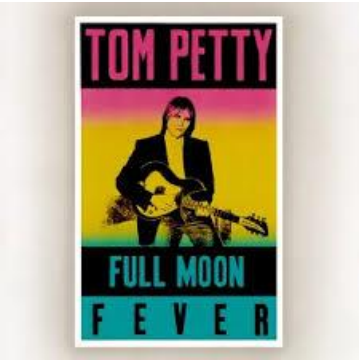
Meanwhile…

- Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products (1/18/2017)
- FDA “won’t back down”
  - 13 pages on why FDA rules advance health
  - 8 + pages rejecting alternative approaches



Conclusion

- Questions?
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