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Internet Issues for FDA-Regulated Industry – A Review of Issues Involving Social Media

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Michael A. Swit, Esq.

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- These slides are intended to provide general educational information and are not intended to convey legal advice.

What I Will Cover

- Legal issues involving FDA regulation of Social Media
- FDA Guidance On Social Media
- FDA actions involving Social Media
- Best Practices and other Lessons

Social Media Today

Social Media – How It Is Being Used

- **Company pages on social media sites:**
  - Facebook
  - Twitter
  - YouTube
  - Tumblr
  - Google+
- **Sites directly sponsored by FDA-regulated firms independent of commercial social media**
  - Blogs
  - Chat rooms
  - Monitored forums

Legal Issues

Food, Drug, and Cosmetic Act ("the Act")

- **Drug and Device Advertising**
  - Ads must be truthful, not misleading, fairly balanced, and have adequate directions for use – can be done via:
    - ***Rx drugs*** – "brief summary" -- § 502(n) of Act
    - ***Restricted devices*** – "brief statement" of intended uses of the device and relevant warnings, precautions, side effects, and contraindications -- § 502(r) of Act
  - Comparative ads:
    - Require substantiation – typically, two adequate and well-controlled clinical investigations

FDA Authority Under the Act

- **"Labeling" --** The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article -- § 201(m) of Act
- **FDA on Internet as Labeling –**
  - Ocean Spray Warning Letter – 2001 – health claims on internet site seen as labeling
  - Del-Immune Warning Letter – 2006 – dietary supplement claims called labeling
- **Difference --** ability to assert jurisdiction
  - OTC drugs, Dietary Supplements, Food, Cosmetics, etc. – labeling
  - Rx Drugs/Restricted Devices -- advertising

FDA Guidance on Using Social Media

- **Virtually non-existent**
  - 1996 – promised guidance on internet – never came
  - November 2009 – Part 15 Hearing
    - still nothing …
  - December 2011 – Draft Guidance on Replying to Unsolicited Requests – relative to social media, said little; on unapproved use:
    - only reply if asked if your product treats an unapproved use; and
    - just give the normal contact at your firm for inquiries
- **FDASIA (Food & Drug Administration Safety & Innovation Act; July 2012) –** mandates a guidance within two years -- § 1121

FDA Guidance

Finally… Draft Guidance – January 2014

- ***Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*** ***[Hot Link]***
- **Guidance answers questions of:**
  - when you are responsible for third party sites – promotion done on "your behalf"
  - how to handle the challenges of 2253 submission for constantly changing S.M. promotion sites that you are responsible for
  - clarifies your responsibility for User Generated Content (UGC)

Finally… Draft Guidance – January 2014 …

- **2253 submission –** FDA will exercise enforcement discretion as to "time of dissemination" duty if you handle per draft guidance
- **General rule on how FDA looks at whether you are responsible for social media --** you or someone acting for you influence or controlled the product promotional activity. ***More specifically:***
  - sites you own, control, create, influence or operate
    - influence – "in any particular" – even if limited in scope
      - ***Example***: firm collaborates on or has editorial, preview, or review privilege over content

Finally… Draft Guidance – January 2014 …

- **When you are responsible for third party sites:**
  - if have influence, even if limited
  - however, financial support alone is not enough
  - if you only provide promotional material to a 3P site, but don't control where it goes, you are only responsible for submitting a 2253 on what you gave the 3P site
    - however, if you suggested where it goes on the site, that = influence
    - "any control" – you have to submit to FDA (presumably that part that relates to your product – guidance is not clear here)

Finally… Draft Guidance – January 2014 …

- **You are responsible for content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product even if on a 3P site**
  - examples: paid speakers; medical science liaison
  - FDA recommends you be transparent about your relationship with an agent that posts for you on a 3P site
- **New view on UGC outside your control – regardless of where posted:**
  - Firm "generally not responsible for UGC that is truly independent of the firm" … even if on "firm-owned or firm-controlled venues"

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Timing of 2253 Submissions for S.M. Sites

- **Your sites –** at Initial display of site **–** submit entirety of website, including interactive and real-time components
  - *note* – not clear to me precisely what FDA meant be "real-time components" (not defined)
  - Include notations to describe part that are interactive and allow for real-time communications
  - Later changes – submit at time of initial display
- **3P Sites on which a firm's participation is limited to interactive or real-time communications**
  - Submit home page of 3P site, along with the interactive page within the 3P site, and the firm's first communication, at time of initial display

Timing of 2253 Submissions for S.M. Sites …

- **Once a month – submit an updated listing of all non-restricted sites for which:**
  - You are responsible (i.e., yours)
  - You remain an active participant in and that include interactive or real-time communication
  - What to submit (can be on a single 2253):
    - Separate document for each site
      - Site name, URL, date range
      - Cross-reference to the date of the most recent submission of site
  - If cease to be active on a site, you should inform your FDA center (CBER, CDER or CVM) by "general correspondence" of that fact.

Timing of 2253 Submissions for S.M. Sites …

- **Restricted sites – monthly:**
  - Must submit all content related to the discussion
  - Via screenshots or other visual representations, including the interactive or real-time communications

June 2014 – Draft Guidance on Internet/Social Media with Space Limits

- Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices *[Hot Link]*
- **Two Key S.M. arenas impacted:**
  - Twitter
  - Sponsored Links on Google, Yahoo, etc.

6/14 DG on Web/SM w Sp Lmts …

- **Two Key Underlying Principles to FDA's Approach**
  - If you make a benefit claim, **must** balance with risk information within the space limitations
  - must provide a mechanism to allow direct access to a more complete discussion of the risks of the product (the "One Click Rule"?)
- **Benefit information**
  - must still be accurate, non-misleading and reveal material facts within the space limitations
  - risk information must accompany benefit within the space limits
  - if can't fit risk and benefit (and link to full info) in space, don't use

6/14 DG on Web/SM w Sp Lmts …

- **Risk Information**
  - Must be comparable in scope to the benefit info. Two factors viewed by FDA:
    - does the risk info qualify the benefit info?
    - was risk info placed with prominence and readability comparable to benefit info?
  - Must appear with benefit info
  - Must include the ***most serious risks*** of the product
    - Rx Drug –
      1. ***boxed warning*** 2. ***all fatal or life threatening risk***
      3. ***all contraindications***
      4. if **1, 2 & 3** not present, most significant warnings or precautions

6/14 DG on Web/SM w Sp Lmts …

- **Risk Information …**
  - Must include the ***most serious risks*** of the product …
    - Animal Drug
      - Potential injury to human handlers/animal patients
      - risk of drug residues entering food supply
    - Devices
      - if particular risk is linked to a specific population type or use of the device, that should be revealed
  - Must include a separate hyperlink on the risk involved
    - Can use "tinyURL", but FDA prefers the URL highlight the risk, such as "**www.SILENZ.com/risk**"
    - risk hyperlink should go to a separate "landing pad" dedicated to risk (and not benefit)

6/14 DG on Web/SM w Sp Lmts …

- **Risk Information …**
  - Prominence of risk info must match that of benefit info, including considering formatting
    - Brief summary – can be handled via a link (FN 16)
- **Example:**
  - Sponsored link:

Headhurtz (ouchafol) [*20/25*]
www.headhurtz.com [*17/ 35*]
For severe headache from traumatic brain injury [*47/ 70*]
Boxed warning [*13/25*]
Potential for brain swelling [*28/35*]
Warning [*7/25*]
Life-threatening drop in heart rate [*35/35*]
Warning [*7/25*]
Potentially fatal drug reaction [*31/35*]
Risk information [*16/25*]
Important safety information [*28/35*]

6/14 DG on Web/SM w Sp Lmts …

- **Example**
  - Twitter:

    NoFocus (rememberine HCl) for mild to moderate memory loss-May cause seizures in patients with a seizure disorder www.nofocus.com/risk [*134/140*]

- **Other Product Information**
  - Generic name of ingredient – still required -- see above example under Twitter – to right or directly below (e.g., sponsored link)
    - make sure both brand and generic are on the "landing pages"
  - Dosage form and quantitative ingredient information
    - required in ad per 502(n) of the Act
    - DG – can put on landing page

June 2014 – Draft Guidance: Correcting Third Party Posts

- **Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices** ***[Hot Link]***
- **No duty to correct** -- if on your SM page. However, DG applies ***only to*** **prescription** drugs and prescription medical devices.
  - Why? Not articulated
  - My guess – the "learned intermediary" due to need for Rx

6/14 – DG on Correcting 3P SM Misinfo …

- **UGC = User Generated Content**
- **General rule – not responsible for 3P UGC; but what does this mean in the DG?**

> However, a firm's control over, involvement with, or influence over a product-related communication, even when generated by a third party, may result in the firm being responsible for the information as a promotional communication. Thus, firms might be responsible for UGC that they solicit or influence, regardless of the forum.

- **Key policies in the DG**
  - correcting is voluntary
  - if you correct in a truthful and non-misleading way, FDA does not intend to object if ***appropriate corrective*** info does not otherwise meet regulatory requirements.

6/14 – DG on Correcting 3P SM Misinfo …

- **"Appropriate Corrective" Information**
  - Be relevant and responsive to the misinformation
  - Be limited and tailored to the misinformation
  - Be non-promotional in nature, tone, and presentation
  - Be accurate
  - Be consistent with the FDA-required labeling for the product
  - Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs

continued …

6/14 – DG on Correcting 3P SM Misinfo …

- **"Appropriate Corrective" Information …**
  - Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author)
  - Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.
- FDA required labeling should either be included or provided in a non-promotional link that goes directly to the labeling

6/14 – DG on Correcting 3P SM Misinfo …

- **Forums**
  - FDA – don't have to correct ALL misinformation
    - agency recognized that these are very difficult to monitor
  - But, company doing a correction should make clear what part it is correcting – a "clearly defined portion" –
    - should date the correction
    - but must correct all misinformation in that "clearly defined portion"
- **Don't have to submit corrections to FDA**

Absent Guidance, Focus on FDA Key Issues

- **Safety**
  - Omitting product health risk
  - Minimizing risk associated with a product
  - Poor risk communication
- **Efficacy**
  - Not fully communicating an approved indication or use
  - Suggesting better efficacy than approved
  - Expanding indication or suggesting unapproved use
  - Misleading data presentation (e.g., cherry picking)
  - Unsubstantiated comparative claims

FDA Actions Involving Social Media

FDA – Alleged Facebook Violations

- **Nenningers Naturals – Warning Letter (12/14/11)**
  - www.triplefludefense.com
  - Allegation – **unapproved drug claims**
    - directly made by company
    - Testimonials
  - Facebook posting of 9/9/11:
    - "School has started! Now is the time to think about flu prevention …"
  - Twitter – same as FB statement

Facebook Allegations …

- **ISBA/Akirmax Pharmaceuticals -- Untitled Letter (2/24/2014)**
  - Drug: TIROSINT (levothyroxine sodium)
  - Allegations:
    - NO risk information
      - product has a Boxed Warning
      - misleadingly suggests product is safer than has been proven
    - Omitted material facts
      - failed to qualify that the drug is not useful in all types of transiet hypothyroidism

Facebook Allegations ...

- **Nature's Rite, LLC – WL (9/19/11)**
  - www.mysleepapneacare.com
  - Allegation -- unapproved drugs: Sinus Support™ Respiratory Relief™ ♦ Herpes Relief™ ♦ Shingles Relief™ ♦ Joint Relief™
    - direct claims
    - testimonials
  - Facebook – sponsored by company – also makes disease claims on sinus care products

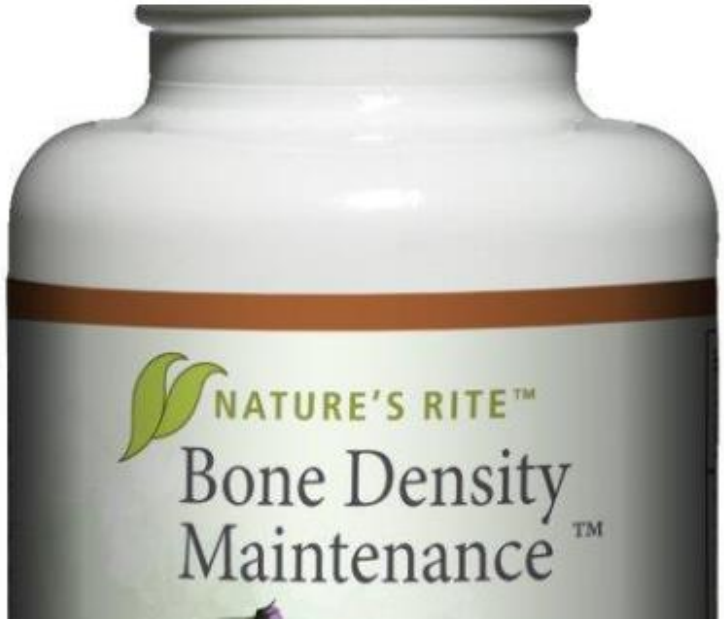
facebook Natures rite Michael A. Swi

ATURI Nature's Rite Natural Reme... Timeline Joined Facebook Highlights Like Crea

Like · Comment

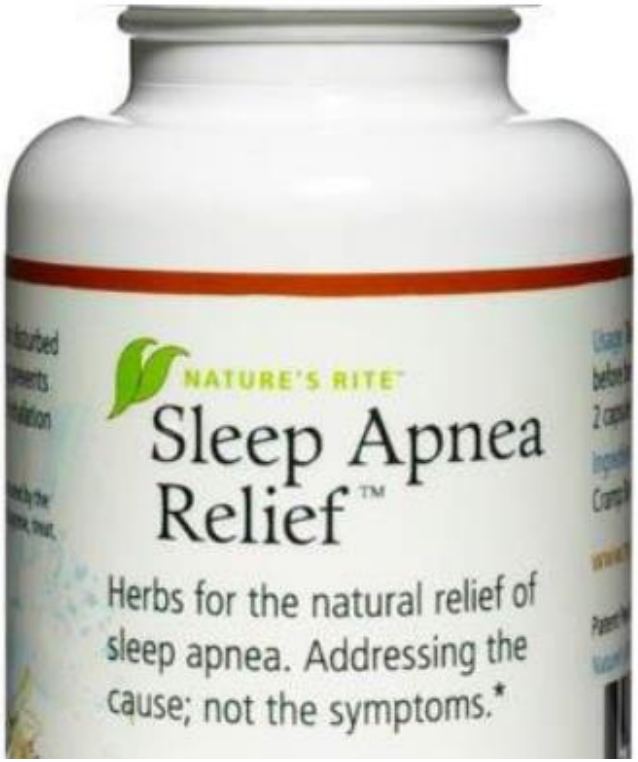
ATURI **Nature's Rite Natural Remedies**
April 2, 2010

Bone Density Maintenance--stimulates the hormonal workforce provides the material needed to rebuild healthy bone!



ATURI **Nature's Rite Natural Remedies**
April 2, 2010

Sleep Apnea Relief--eliminating the symptoms of Sleep Apnea by treating the cause



Now
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Join

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Facebook Allegations …

- **For Earth, Inc. – WL (8/19/11)**
  - www.migenetics.com
  - Allegation –
    - Unapproved drugs: Zinc for sickle cell anemia ♦ Vitamin D for hypertension ♦ Vitamin B5 for alopecia and Alzheimer's
    - Unauthorized health claims: Vitamin D for reducing risk of developing breast cancer

Facebook Allegations …

- **For Earth, Inc. WL:**
  - Facebook violations:
    - claims – posted by company – with links back to company website
    - testimonials – two by same poster -- attributed to company
      - "Everything I have used to prevent my cancer from coming back and every supplement I use to heal my body from chemo is in MiGenetics."
      - "The right ingredients (supplements) have kept me from death due to cancer …"

Facebook Allegations …

- **Cellular RX – WL (5/25/11)**
  - www.cellpro7.com
  - Allegation – unapproved drug: arthritis, asthma, COPD, reduction in PSAv counts
  - Facebook
    - testimonials, including videos
      - "when I started taking OM24®, within days my osteoarthritis was relieved…."
      - "I totally control my diabetes and blood pressure with the tablets"

Tasigna and the "Facebook Share" Widget

- **Novartis Untitled letter – July 2010**
  - "Share" feature on Tasigna website allowed the sharer to make comments and post those on FB with content from the Tasigna website. FDA claimed that this:
    - omitted risk information
    - broadened the indication
    - made unsubstantiated superiority claims
  - Boxed warning drug w/REMS program
  - Link back to Tasigna site is not adequate for risk

"Liking" An Unapproved Drug Claim on FB

- **AMARC Enterprises – Dec. 2012**
  - WL:

We also note claims made on your Facebook account accessible at: https://www.facebook.com/poly.mva, which includes a link to your website at www.polymva.com. The following are examples of the claims:

In a March 10, 2011 post which was "liked" by "Poly Mva":

"PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation…Thank you AMARC"

Sponsored Link Violation

- **Gilead Untitled Letter – (6/27/14)**
  - (*note*: after the June "space limits" DG issued on 6/17/14)
  - Sponsored link:

    - **Hepatitis B Prevention** – viread.com
      www.viread.com/Treating HBV
      Looking for A **Hep** B Treatment Option? Click to Learn More!

  - FDA:
    - Unapproved new use – "prevention" – approved use is to treat
      - thus, lacks adequate directions for use
    - No risk info at all, but drug has a boxed warning for fatal lactic acidosis
    - No generic name and not submitted on 2253

YouTube Citations

- **QLaser Healing Light – WL (3/3/11)**
  - Allegation – uncleared uses for laser product that had been cleared under a 510(k) for pain: "re-energize brain and heart cells…" ♦ "… for the treatment of any unknown condition…"
  - YouTube:
    - Statement in a video – "There's just unlimited things that the laser will do from migraines to asthma to sciatic nerves." [same video also on website]

YouTube Citations …

- **IntelliCell Biosciences – WL (3/13/12)**
  - Allegation: YouTube video states that IntelliCell (an autologous adipose tissue) can be used ***"off-label to treat various patient ailments"*** such as wrinkles, osteoarthritis, gum recessions and breast augmentation – "***no safety risk***"
    - unapproved drugs without a BLA
    - http://www.youtube.com/watch?v=sK0G4GE9UZs – ***still up on YouTube as of 3/6/2014***
  - Also had significant GMP deviations

Twitter Allegations …

- **For Earth, Inc. WL –**
  - "Is Graviola the answer to fighting cancer? It could be a big part of it."
- **Nenningers WL –**
  - same statement as cited in WL (see prior slide) also was cited by FDA as being on company's Twitter account

Tumblr

- **The Avalon Effect WL**
  - November 5, 2012
  - Uncleared/approved uses for "Quantum Series Personal Wellness Pack" – including:
    - Lupus, fungal meningitis
    - Lyme Disease, MRSA
  - Hyperlink to an audio recording made by founder of company discussing unapproved uses

Best Practices and Other Lessons

Cautions in Using Social Media

- ***Medium is irrelevant*** -- if FDA requires, e.g., risk information, caution requires it be included as if it were in print. See, e.g., *FDA Draft Guidance – Presenting Risk Information in Prescription Drug and Medical Device Promotion* --
  - ***http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf***
- ***Testimonials*** **– statement by third parties –** no longer will be attributed to you if you control the site – prescription human and animal drugs and biologics – under 1/2014 draft guidance
  - ***BUT*** – view regarding non-Rx devices, OTC drugs, etc., not clear; 1/2014 draft guidance is silent

Cautions in Using Social Media

- ***Have to monitor posts by third parties on your sponsored S.M. sites (even under new draft guidance, I recommend)***
  - Be careful with your celebrity endorsers
  - Consider "PharmaWall" type software that allows you to monitor posts on Facebook before they go up
  - Disable comments (if possible)
    - FB – only if "whitelisted" – brand specific
    - YouTube – is possible

Cautions in Using Social Media …

- ***"Double posts"*** **–** third party poster on your social media site attaches an article about your product that contains unapproved uses or incorrect risk information **–** you may be responsible
- ***How best to ensure compliance in using social media?***
  - ***Don't have one*** – that's the Janssen solution – recently pulled its ***Psoriasis 360°*** page from FB

Other Lessons from Social Media WLs

- ***FDA will follow the links --*** in other words, they won't just look at your website, but will look at all internet-related statements … which leads them to social media
  - The Avalon Effect WL – also cited Avalon for uncleared uses on third-party websites (including Twitter, YouTube, and Facebook) where there was a link back to Avalon
  - Alistrol Health WL (June 26, 2012)
    - FDA citations for unapproved drug claims for dietary supplements included citing company for a (1) Facebook posting that include a link to (2) an article on a blog on (3) the firm's website

Other Lessons from Social Media WLs …

- ***Be careful with metatags* – FDA has cited –**
  - *Nature's Rite WL* -- Metatags cited – "sleep apnea," "herpes, … sinus relief, … asthma…"
  - *BioAnue Labs WL* – (2/9/12) – also cited metatags for unapproved drugs
- ***Make sure the site is down if you say you've stopped improper claims***
  - *QLaser Healing Light LP* WL –
    - June 2010 – company: "terminated" questioned claims
    - FDA – in WL – sites still up in Jan. 2011
- ***Adverse event information* – you must follow up on it, but that can be difficult**

Other Lessons

- **Plan in advance for regulatory challenges of social media**
  - Have robust SOPs to govern:
    - How content is developed, reviewed and approved
    - How to deal with third-party posts to your firm's SM sites
      - Terms of use -- firm reserves right to delete any post for any reason (and without need to provide a reason to poster)
    - Adverse event and complaint follow-up
    - How to respond to requests for information
  - Train personnel on SOPs
  - Audit operations under formal written QA Audit program

Questions?

- ***Call, e-mail or fax:***

Michael A. Swit, Esq.
Special Counsel, FDA Practice
Duane Morris LLP
San Diego, California
direct: 619-744-2215
fax: 619-923-2648
maswit@duanemorris.com

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  - LinkedIn: http://www.linkedin.com/in/michaelswit
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About Your Speaker

***Michael A. Swit, Esq.*, is a Special Counsel in the San Diego office of the international law firm, Duane Morris, LLP, where he focuses his practice on solving FDA legal challenges faced by highly-regulated pharmaceutical and medical device companies. Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences. His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics and therapeutic biotech products. Mr. Swit has been addressing vital FDA legal and regulatory issues since 1984, both in private practice with McKenna & Cuneo and Heller Ehrman, and as vice president, general counsel and secretary of Par Pharmaceutical, a top public generic and specialty drug firm. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms. He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board. He earned his A.B., *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University.**