NEW PRODUCT LAUNCHES & THE PRE-LAUNCH PERIOD: STRENGTHENING THE PARTNERSHIP WITH THE BUSINESS

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AGENDA

- Introductions
- Background on Preapproval Promotion
- Timing, Staffing, Promo Materials for Launch
- KOL Relationships
- Formulary Committee for New Products, Managed Care
- Disease State Campaigns
- Publication Planning
- Market Research, Focus Groups, Analytics of Open Payments Data
- Open Q&A

BACKGROUND: PREAPPROVAL PROMOTION

FDA REGULATION OF PRODUCT COMMUNICATION

- FDA's authority to regulate the manufacture, sale, and distribution of drugs in the United States includes oversight of labeling and advertising for all prescription drugs.
- As a result, FDA has broad authority to regulate communications by drug companies regarding the safety and efficacy of drugs and technologies under development prior to marketing approval.
- The purpose of these FDA restrictions is to: (1) preclude commercialization of the drug or technology before it is approved; and (2) prevent potential customers (patients/physicians) of the drug or technology from developing unsubstantiated beliefs about the drug's or technology's safety or effectiveness.

PRE-APPROVAL PROMOTION DEFINED

- 21 C.F.R. § 312.7(a).
- *Promotion of an investigational new drug.* A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution. (Emphasis added.)

SCOPE

- FDA's authority includes oversight of labeling for all prescription drugs and biologics.
  - "Labeling" is defined broadly to include "all written, printed, or graphic matter upon an article or container or accompanying such article." 21 U.S.C. 321(m)
- This means pre-approval promotion in the form of:
  - Oral statements
  - Brochures
  - Websites
  - Mailings
  - Detailing pieces
  - Price lists
  - Catalogs
  - Order forms

… *is prohibited*

TIMING

- FDA has not made an official statement regarding safety and efficacy of a drug until **final approval.**
  - Indications near the last few months of review that approval is imminent and tentative approval by the Agency do not permit promotion.
  - Until final approval is issued, a product cannot be promoted as safe and effective.

TIMING

- Launch Advisories
  - First 120 days of Marketing to Public (not yet in the public domain)
  - Prior to First Use
  - Applies to new drug, indication, delivery system, formulation, or route of administration
  - Specific Materials: Press releases, Ads, Sales Aids, Patient Brochures, Websites
  - Identify as: Launch Core, Launch Non-Core, Non-launch
  - Page limits (12pp for websites and patient brochures / 4pp for print ads)
  - FDA review time frame: 45 days
  - One consolidated “submission” / Do not submit on 2253

PERMISSIBLE COMMUNICATIONS

Examples:

- Scientific exchange, e.g., CME programs
- Dissemination of scientific journal articles in accordance with FDA's Guidance
- Investor communications, subject to certain limitations
- Communications about the company's areas of research and developing technologies, i.e., communications that do not involve the discussion of specific products
- Disease state awareness communications
- Advisory Meetings / Focus Groups, subject to certain limitations
- Communications intended for the recruitment of clinical study investigators and subjects

EXCEPTIONS FOR LIMITED PRE-APPROVAL COMMUNICATIONS

- FDA permits limited pre-approval advertising for investigational drugs and biologics:
  - **"Institutional" advertisements** that state a specific drug company is conducting research in a certain therapeutic area to develop new and important drugs. (May not mention drug name)
  - **"Coming soon" advertisements** announce the impending availability of a named drug product. (May not include information on intended use, safety, or effectiveness.)
- A sponsor may use *either* institutional or coming soon advertisements for a drug, but not both.
- These ads are generally permitted within six (6) months of introduction of the product.

EXCEPTIONS FOR LIMITED PRE-APPROVAL COMMUNICATIONS

- **Scientific Exchange.** Companies can engage in the legitimate exchange of scientific information regarding the drug and unapproved uses, including communication of scientific findings in scientific or lay media and continuing medical education—but these communications cannot cross the line into promotion and must be independent of the manufacturer's influence.
- **Clinical Trial Recruitment.** Sponsors can recruit patients and clinical investigators for trials, but cannot make claims of safety or efficacy in recruiting materials.

ENFORCEMENT

- Failure to adhere to 21 C.F.R. § 312.7 is violation of IND regulations and may result in termination of IND or other enforcement (21 CFR § 312.44(b)(1)(v)).
- If a product is promoted prior to approval, FDA will consider it "adulterated" and/or "misbranded."
- FDA can take enforcement action against adulterated and misbranded products.

ENFORCEMENT

- When FDA determines that a product is misbranded or adulterated, it can:
  - Issue warning letters or untitled letters;
  - Require the product to be recalled;
  - Impose civil money penalties;
  - Seize the violative product;
  - Prohibit the violative conduct (injunction) and require companies to enter into consent decrees regarding future behavior; and
  - Criminally prosecute offender.

ENFORCEMENT

- At least 10% of OPDP's enforcement letters in the last four years have cited companies for pre-approval promotion.
- FDA has a long history of issuing warning and untitled letters to companies that attempt to "seed" or prepare the market for a drug prior to approval.
- A large volume of FDA enforcement actions for pre-approval marketing have also been issued in cases of investor communications and the clinical investigator context where special exceptions to the prohibition on pre-approval communication exist.
- There is no exception to the prohibition in the context of field force initiated discussions.

EXAMPLES OF COMMON VIOLATIONS

- Statements implying safety or efficacy of an investigational product;
- Failure to disclose material risk information in light of representations;
- Statements comparing an investigational product to an approved product;
- Misleading statements about statistical data based on clinical trial results;
- Conclusive statements about safety and efficacy demonstrated by clinical trial results; and
- Misleading statements about the safety profile, adverse events, or risks.

LAUNCH PLANNING, ACTIVITIES & MATERIALS

TOP 10 KEY LAUNCH ACTIVITIES

1. Commercial Team Staffing
2. Market analysis & feedback on clinical data (from KOLs)
3. Share info across entire launch organization
4. FDA acceptance of filing (Target PDUFA/ standard vs priority review)
5. Decision for "Coming soon" – dependent on trade name acceptance (EU vs USA risk), (Global vs Regional brand name) or Disease state education
6. First round label negotiations with FDA
7. Prepare draft launch marketing materials
8. Risk assessment of pre-clear vs no pre clear
9. Start work on Speaker Bureau ~3-6 months prior to expected approval
    1. Train speakers as close to PDUFA as possible
10. Launch meeting to train sales representatives on label and messaging

Hold your breath… first 12 weeks determine trajectory of brand!

PRE & POST PDUFA CONSIDERATIONS

PDUFA

Pre-Approval Materials

Now approved campaign drives awareness with a focus on communicating core messages

- Advisor & Steering Cmte Feedback
- Coming Soon OR Disease Education Campaign & Collateral
- Campaign Rollout
- Build Bureau & Train Speakers
- Launch Meeting Training Materials

Now Approved

Now approved campaign drives awareness with a focus on communicating core messages

- Dr. Doctor Letter Now Approved Awareness)
- Launch Broadcast + Collateral
- Journal Ad
- Now Approved Website
- Online (email, banner ads, etc)
- Convention Panels

OPDP Submission

Post 90 days of label team will submit core promotional resources for OPDP review

+90 Days

+120 Days – Full Launch

Full Launch Materials

- Master Visual Aid
- MOD/MOA Animation
- FAQ
- Patient Education Brochure (partnership w/advocacy)
- Case Studies
- Importance of ABC Brochure

Full Launch

- Product.com
- Journal Ad/ Advertorial
- MOA Video
- Case Study Videos
- KOL Videos
- Online (email, banner ads, etc)
- Convention Activities

KOL RELATIONSHIPS

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- Receiving early feedback from key opinion leaders is extremely important to inform commercial approach to promotion
- Prior to approval, the commercial organization will likely engage KOLs, in advisory board meeting settings
  - When conducted appropriately, these meeting are extremely valuable to **receive** feedback from the community
- Important Considerations:
  - Is this a new or existing disease area for the company?
    - New relationships vs. existing relationships
    - Establishing Fair Market Value Rates
      - National or Regional? (This can be painful)
  - Prior to approval, the company is the recipient of feedback at these meetings
  - Avoid pushing data or potential product messages to HCP's prior to an approved label
    - This approach, can be considered pre-approval promotion
  - Important to train entire company staff on the appropriate way to address questions received from KOLs at meetings

FORMULARY COMMITTEE FOR NEW PRODUCTS & MANAGED CARE

DISEASE STATE CAMPAIGNS

PUBLICATION PLANNING

MARKET RESEARCH, FOCUS GROUPS & OPEN PAYMENTS DATA ANALYTICS

QUESTIONS?

THANK YOU!