

Regulatory Considerations in Product Development

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- **This outline is intended to support an oral briefing and should not be relied upon solely to support any conclusion of fact or law.**
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Establish FDA Strategy Early!!

Some considerations follow . . .

REGULATORY PLANNING

- *Create A Project Plan With Well-defined Go/No-go Decision Points –*
 - **Difficult, But Vital To Know When To Shift Gears.**
 - **Plan With The End In Mind** – your ultimate labeling will drive what you need to do – create a “Product Profile” early and try to stick to it.

PLANNING ...

- ***Make Sure You Are Ready To Go From “R” to “D”***
 - **Internally** - people and systems; change in mindset from research to development.
 - **Drug Formulation or Device Design Has Been Rigorously Reviewed** -- so as to optimize your chances when going into humans.
 - Device – needs design controls under QSR regulations
 - **Once Clinical Evaluation Begins, Preclinical Efficacy Experiments** -- should be limited or undergo rigorous review and oversight.
 - **Educate Scientists And Researchers** – on the realities of the demands of development, especially documentation
 - *Example* -- **report writing** -- may be a weakness in research, but is important in development. Start early in the process.

PLANNING ...

- *Make Sure Regulatory, Clinical, And Sales & Marketing Are All Talking Early On –*
 - **Ensure Indication or Intended Use (thus, Endpoints) Being Studied Is One You Want To Sell**
 - **Some Consideration**
 - **Study Design** –while marketing may want superiority if you go for that sort of study and fail, the FDA won't let you reanalyze the study for non-inferiority -- hence failed development program...
 - **Indication Choice** – consider limited initial indication that can be the starting point for subsequent bigger indications
 - can be key to optimal product lifecycle management

PLANNING ...

- *Beware of "Divergent Evolution" between Product Development and Intellectual Property Efforts!*
 - **How Patents Can Evolve**
 - Attaining patent protection for a novel chemical entity or formulation is a multiyear process,
 - In process, claims often become more limited in number and in scope, due to prior art, Patent Examiner concerns, etc
 - **Ensure A Strategic Linkage Between The Product Development And Patenting Efforts** -- to best assure:
 - Patent(s) granted actually cover critical features of the product being studied in clinicals
 - Clinicals actually cover patented/able claims

PLANNING ...

- *Understand Approval Is Not Enough, Somebody Has to Pay for It!!* - coverage (on formulary) and reimbursement (at a reasonable copay tier).
 - Some keys:
 - Label claims -- Is there anything novel you can say?
 - Comparative effectiveness:
 - future of reimbursement
 - future for competitive/comparative claims – clinicals will be needed (FDA/FTC)

PLANNING ...

- ***Other Key Planning Efforts***
 - **Product Name** –
 - Globalize the product name (be careful with different meanings)
 - Seek regulatory agency concurrence early.
 - **Find Collateral Support**; e.g., Patient Groups, Thought Leaders
 - can help with identifying investigators
 - can help with patient recruitment
 - **Identify Enemies** -- commercial and otherwise (e.g., special interest groups)
 - Anticipate their moves (e.g., Citizen Petitions)
 - **Pediatric Assessments** -- -need a plan to address pediatric usage if a drug or biologic

PLANNING ...

- *Management*
 - **Must Understand Process.**
 - **Must Support Company's Quality System, Especially As A Company Matures.**
 - **Don't Let Financial Milestones Drive Development** – recipe for disaster (e.g., Refuse To Files, Clinical Holds).
 - **Contrast:**
 - “What is the minimum we need to do to get approval?”*
 - vs.*
 - “What is necessary for us to provide in order to get a first cycle review approval”.*
- [if your CEO thinks first option is OK, time to update your CV]

WORKING WITH FDA

- *Early interaction* -- essential to understanding your path and what you need in your kitbag
 - **FDA encourages and appreciates** (usually) being consulted early in the development stage -- helps build a relationship with Agency that can pay off during the approval process.
 - **Take advantage of all Regulatory “value-added” initiatives** – e.g., on drug side, Fast Track, Accelerated Approval, Orphan Drug, Special Protocol Assessment (but be careful on this)

WORKING WITH FDA ...

- *Ensure You Get Agency Agreement On Exactly What Is The Indication* – will drive related labeling language, especially if related to disease, treatment or metrics
 - Example: “Chronic sinusitis”
 - Not in DSM or accepted text books -- really a term of art among ENTs.
 - Company
 - started clinical trials,
 - Then, went to FDA – *“we’re treating chronic sinusitis!!”*
 - FDA -- **“what’s’ that?”** -- leading to a rather lengthy debate about symptomatology of “chronic sinusitis”.
 - **Result** – company had already studied something not entirely covered by the now agreed upon definition of “chronic sinusitis” both as to:
 - outcomes
 - method of measuring
 - **Consequence** – also can end up proving a labeled indication that does not jibe with original marketing projections

WORKING WITH FDA ...

- *Safety is Lynchpin Today* –
 - Focus On Signals/AE's Early
 - Ensure personnel evaluating are qualified
 - “REMS” –
 - “Risk Evaluation and Mitigation Strategies”
 - Future is now – due to Food & Drug Administration Amendments Act of 2007 –
 - You need to control REMS process; don't let FDA
 - Example: anticipate Phase IV, Post-Approval Study, but drive its design

WORKING WITH FDA ...

- ***Listen!!***
 - **If You Get Regulatory Agency Advice -- Do It!**
(well, almost all the time)
 - Failure to adhere to any given advice may only subsequently antagonize the reviewer.
 - **Caveat --** If you don't want to do it or think it's wrong, engage FDA **promptly** to gain its buy-in to your position
 - Don't just ignore FDA and go down your own path
- ***Keep your Promises!!***
 - **A sure way to lose credibility – fail to deliver what you promised**

SUBMITTED QUESTIONS

Regulatory Questions

- **What is the likelihood that the FDA will require a companion test for targeted therapies?**
- **Discuss value of early, informal meetings with FDA.**
- **Discuss orphan drug status, and what it means regarding FDA approval.**
- **What are the best strategies for obtaining FDA approval, alone or with partner or through help in NIH funding?**

Regulatory Questions ...

- In cancer diagnostics, does a service (e.g. detection of cancer cells in patients, chemo-sensitivity testing, selection of therapeutic agents using patient's cancer cells etc..) to oncologists or physicians for their treatment decision-making require an approval by the FDA? If so, how to obtain such approval (not for FDA clearance – 510k or approval – premarket application)?

Regulatory Questions ...

- How do you achieve “buy-in” from hospitals or other customers to achieve reimbursement for a medical device? i.e. the device has been tested and proven in a lab-setting (say reduce bacteria in-vitro), but full data on the cost-savings to a hospital (reduce infections) is not fully proven.
- Navigating the FDA vs other routes (i.e. achieving approval in Europe first)

Questions after the Conference?

Call, e-mail, fax or write:

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About your Speaker ...

Michael A. Swit, Esq. develops and ensures the execution of a broad array of regulatory and other services to his clients. His expertise includes regulated product development strategies, compliance and enforcement initiatives, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for drug, biologic, device, IVD, and other life sciences companies, as well as those in the food and dietary supplement industries.

Mr. Swit has been addressing critical FDA legal and regulatory issues since 1984. His vast and multi-faceted experience includes serving for three and a half years as corporate vice president, general counsel and secretary of Par Pharmaceutical, a prominent, publicly-traded, generic drug company and, thus, he brings an industry and commercial perspective to his work with FDA-regulated companies. Mr. Swit then served for over four years as CEO of FDANews.com, a premier publisher of FDA regulatory newsletters and other specialty information products for the FDA-regulated community. His private FDA regulatory law practice has included service as Special Counsel in the FDA Law Practice Group in the San Diego office of Heller Ehrman White & McAuliffe and with the Food & Drug Law practice at McKenna & Cuneo, both in the firm's Washington office and later in San Diego. He first practiced FDA regulatory law with the D.C. office of Burditt & Radzius.

Mr. Swit has taught and written on a wide variety of subjects relating to FDA law, regulation and related commercial activities, including, since 1989, co-directing a three-day intensive course on the generic drug approval process and editing a guide to the generic drug approval process, *Getting Your Generic Drug Approved*. A former member of the *Food & Drug Law Journal* Editorial Board, he also has been a prominent speaker at numerous conferences sponsored by such organizations as RAPS, FDLI, and DIA. He received his A.B., *magna cum laude*, with high honors in History, from Bowdoin College and his law degree from Emory University School of Law. Mr. Swit is a member of the California Bar.