

TO: ARIZONA ASSOCIATION OF HEALTH CARE LAWYERS
FROM: Jerry Gaffaney, President, Secretary/Treasurer
DATE: January 11, 2016

JANUARY 27, 2016 PROGRAM ANNOUNCEMENT

“Advancing Biotech Innovation: The Ins and Outs of Collaboration Arrangements and Licensing Agreements”

Date: January 27, 2016
Time: 12:00 noon to 1:00 pm
Place: Lewis Roca Rothgerber Christie at Collier Center
201 East Washington Street, 3rd Floor

Program Description: This Program will explore product development, from innovation/start-up to commercial launch, and the various collaborative arrangements that typically accompany this process. Among the topics to be covered are (i) initial collaborative discussions (scientific, business, investment); (ii) testing and research relationships (CRO and University); (iii) collaborative development; and (iv) clinical trials. Key agreements and agreement considerations tracking these relationships will be discussed.

Our speakers are Angela Perez and Bill Mulholland both with Snell & Wilmer.

Angela Perez. Angela is a transactional attorney whose practice is concentrated in corporate and securities and she is also the co-chair of Snell & Wilmer's Life Science and Medical Technology Industry Group. She has extensive experience in representing biotechnology, life science, medical technology and pharmaceutical companies, including those developing and marketing drugs, diagnostics, medical devices, laboratory tests and genetic tests. As such, Angela commonly drafts and negotiates commercial agreements involving testing; sponsored research; clinical trials; clinical supply; manufacturing; licensing; joint development; and other collaborative arrangements.

Bill Mulholland. Bill is an intellectual property attorney and is also the co-chair of Snell & Wilmer's Life Sciences and Medical Technology Industry Group. His past experience includes serving as in-house counsel for pharmaceutical and agribusiness-based industries. A substantial portion of Bill's practice involves strategic counseling for these industries, including all IP-related aspects of discovery, development and commercialization activities. He has extensive transactional experience and has successfully negotiated a wide range of licenses and other agreements in support of various industry and university alliances. Bill's life sciences practice includes small molecule chemistry and biologic therapeutics, as well as diagnostics, drug discovery and drug delivery. His agribusiness practice similarly focuses on chemical and biologic-based active ingredients, as well as formulation and chemical process technologies.

This program will be held on January 27, 2016 at 12:00 noon at Lewis Roca Rothgerber Christie's office in Phoenix. Lunch will be served - \$10 for AAHCL members/\$15 for non-members.

Please RSVP in advance by e-mail to CLovejoy@dickinsonwright.com. You may pay at the door or send your check in advance (payable to AAHCL) to Jerry Gaffaney, Dickinson Wright 1850 North Central Avenue, Suite 1400, Phoenix, Arizona 85004. Whether or not you pay in advance, you must RSVP prior to the program.

This program will count for one (1) credit hour of continuing legal education.

CALL IN INFORMATION: To access the teleconference, use any of these dial-in numbers: 1-866-496-2887, 602-262-5301 or 602-385-0230. Enter this Bridge number: 5218. Enter this Participant PIN number: 95218

For CLE credits and materials for this program, please contact Cyrie Lovejoy.

OFFICE DIRECTIONS – www.lrrc.com/phoenix#directions

Take I-10W to Washington Street. Exit and turn left at Washington Street for 2 miles and follow it to Collier Center (Bank of America building, including Kincaid's and Hard Rock Café), located on the south side of Washington Street. Turn left into the parking garage just before 2nd Street. Collier Center is on the southeast corner of 2nd Street and Washington.

Take the garage elevators up to the 2nd floor (Collier Center Lobby), then take the second bank of elevators to Lewis Roca Rothgerber Christie's 3rd floor for the AAHCL Meeting.

Advancing Biotech Innovation: The Ins And Outs Of Collaboration Arrangements and Licensing Agreements

Presented by:
Angela L. Perez
William F. Mulholland, II

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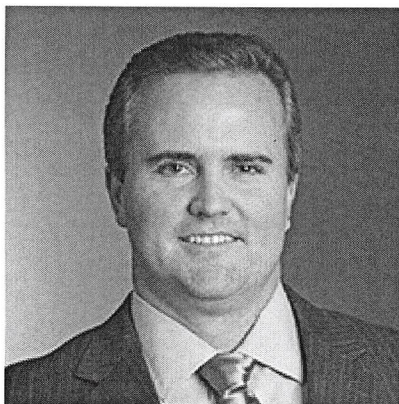
Angela L. Perez

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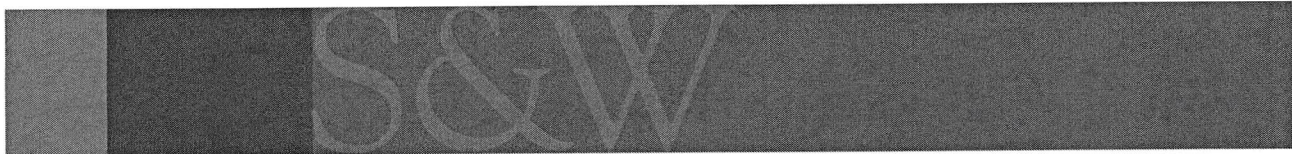
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Life Science and Medical Technology Industry

- Made up of 6 Principal Segments:
 - Drugs, Biologics & Diagnostics
 - Medical Devices & Equipment
 - Research, Testing & Medical Labs
 - Hospitals
 - Bioscience-Related Distribution
 - Agricultural Feedstock & Chemicals



Company Lifecycle

- University Research
- Spin-Out / License
- Corporate Formation & Governance
- Employment Agreements
- Financing



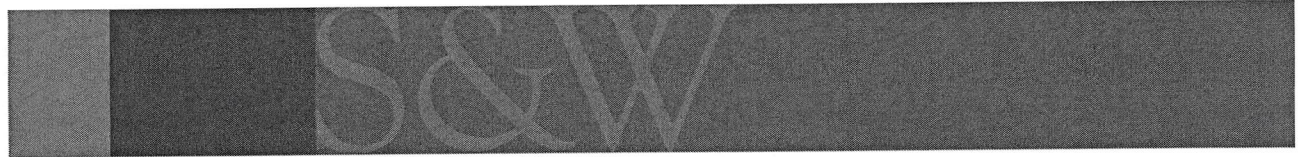
Company Lifecycle

- Manufacture
- Pre-Clinical and Clinical Trials
- Commercial Launch
- Acquisition of Other Companies / Product Lines / Patents
- Sale of Company

Why Collaborate?

- Development costs are high
- Access to capital is low
 - particularly without strong clinical data
- Risks are high
- ROI is slow
 - ~12 yr drug approval process
- Specialists needed
 - Highly specialized requirements of regulatory, legal and patent systems

Collaboration as a solution...



Collaboration Drives Commercialization

- Collaboration Between Pharma and Biotech
 - Pharma looking to minimize risk and expense of identifying new drugs
- **Collaboration Between Biotech and Hospitals**
 - Biotech looking to advance the science / data;
 - gain access to cell lines, patient populations and subject matter experts; and
 - lower the risks associated with investment in their drug / company.... at a low cost.

Stages of the Collaboration

- **Non-Confidential Communications**

e.g. Initial discussions with research hospital concerning pre-clinical cellular and animal studies

- How to get the first meeting
- Only share publicly available information

Stages of the Collaboration

- **Confidential Communications**

e.g. Discuss detailed info re drug properties, indication; research project discussed; protocol/research plan drafted.

- Written Non-Disclosure Agreement
- Breadth and Duration of Restrictions
- **Caution**: an NDA does not settle the issue of IP ownership of work product developed in the course of these discussions or preparation of a scope of work / protocol



Stages of Collaboration

- **Sponsored Research or Testing**
 - Payment Structure
 - Study Scope / Protocol
 - Intellectual Property Rights
 - Consider determining ownership of inventions by Subject Matter
 - Special Representations
 - Publication Rights

Stages of Collaboration

- **Option Agreement**
 - Often negotiated together with Sponsored Research Agreement
 - Permits Sponsor to exercise an option {to negotiate} a license (exclusively) w/ Hospital
 - May require parties to consider details of potential License Agreement up-front, such as:
 - Scope; Field of Use; Reservation of Rights; Royalty Rates
 - Or, details left to be negotiated later



Stages of Collaboration

- **License Agreement**

- Payment Terms

- Up-front Payments
 - Milestone Payments (IND Approval; First enrolled patient in Phase I trials, Phase I completion; Phase II initiation; Phase III initiation, Foreign Clinical Trial; NDA submission; NDA approval)
 - Royalty on Product Sales / Royalty Stacking / Special issues of royalties on platform / delivery technologies

- Field of Use

- Termination



Stages of Collaboration

- **Clinical Trial Agreements**

- Recruitment Deadlines
- Completion Deadlines
- Payment Terms
- Liability
- Privacy
- Intellectual Property