



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

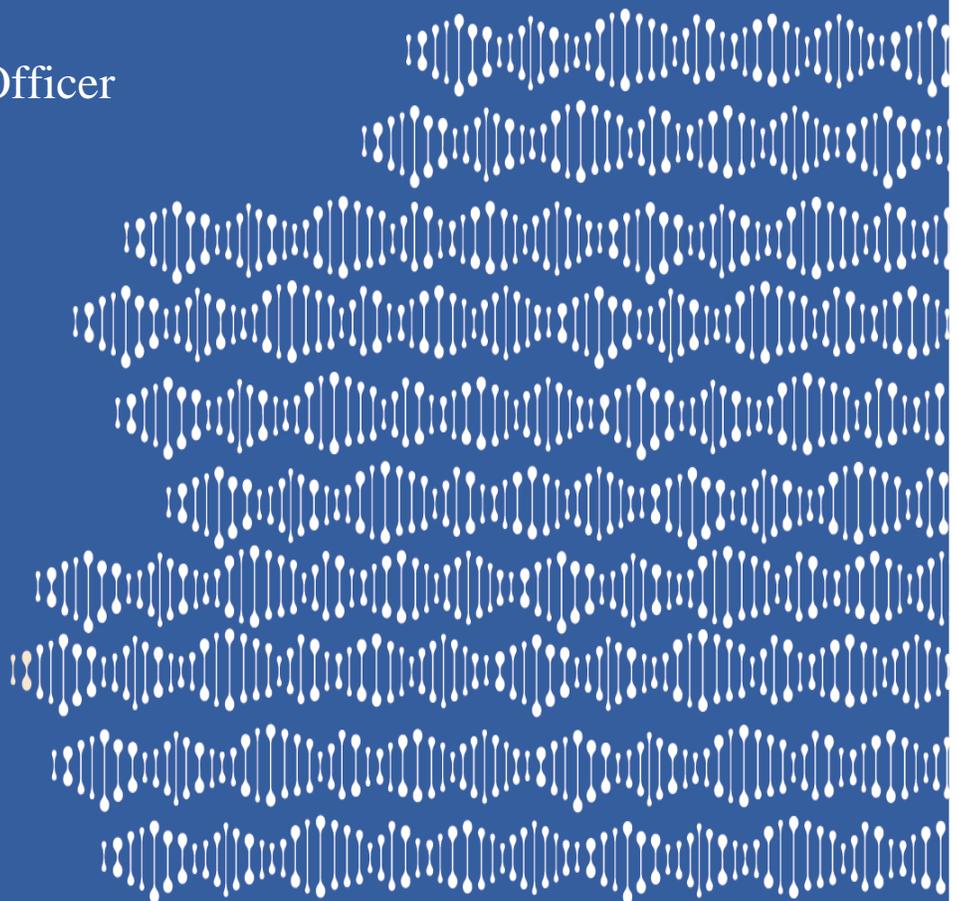
# House Committee on Public Health

April 28, 2015

## Product Development Research Program

Wayne Roberts  
Chief Executive Officer

Updated 4-27-15





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## Texas Constitution, Article 3 (Proposition 15, November 6, 2007)

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### Sec. 67. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS.

(a) The legislature shall establish the Cancer Prevention and Research Institute of Texas to:

(1) make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and to institutions of learning and to advanced medical research facilities and collaborations in this state for:

(A) research into the causes of and cures for all forms of cancer in humans;

(B) facilities for use in research into the causes of and cures for cancer; and

(C) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans;

(2) support institutions of learning and advanced medical research facilities and collaborations in this state in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment; and

(3) establish the appropriate standards and oversight bodies to ensure the proper use of funds authorized under this provision for cancer research and facilities development.



# Texas Health & Safety Code, Section 102.002

## House Bill 14, 80<sup>th</sup> Legislature

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**PURPOSES. CPRIT is established to:**

(1) Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;

(2) Attract, create, or expand research capabilities at institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and creation of high-quality new jobs in Texas; and

(3) Develop and implement the Texas Cancer Plan.



## **CPRIT's Product Development Research Program is Essential to its Mission**

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CPRIT was constitutionally established in part to make grants for translational cancer research that develop therapies, protocols, pharmaceuticals and procedures. Developing a new drug requires an enormous commitment of time and resources—up to 15 years and a \$1 billion investment to get a promising idea from the lab to the bedside to treat patients. CPRIT funds a small but critical amount invested at a time that is usually prior to venture capital or drug investors.

**CPRIT's Product Development Research grants fund specific cancer-related research projects taking place at companies.** CPRIT invests grant funds in early-stage clinical research and development efforts at small biotechnology companies in Texas.

- CPRIT's Product Development Research grants are authorized by the Constitution and state law.
- CPRIT's grant funds are tied to specific research projects and cannot be used for expenses unrelated to the project.

**CPRIT's Product Development Research Program funds innovative ideas and requires measurable results.** CPRIT uses an open, competitive selection process to determine which projects are funded.

- CPRIT's primary criteria in making Product Development Research grant awards are scientific merit and impact on cancer care. Proposed projects are reviewed by independent experts with additional business and intellectual property due diligence assessments a necessary part of the competitive approval process. All reviewers are from outside Texas to minimize potential conflicts or undue influence.
- All companies performing CPRIT projects are scrutinized to ensure sound business and regulatory plans that can attract the follow-on financing necessary to continue developing the drug, device or therapeutic after CPRIT funding ends.
- CPRIT monitors these projects and protects taxpayers' money by paying grantees only a portion of their award at a time, with funding based on successfully achieving established milestones.

**Product Development Research grants grow the Texas bioscience industry and create economic benefits for the state.**

- Companies with CPRIT grants have raised over \$900 million in follow-on funding from outside sources after getting a CPRIT grant; CPRIT companies are thriving and achieving success.
- CPRIT-funded companies are creating highly skilled jobs in Texas.
- The state gets a return on its investment through contractually-required revenue sharing once a successful drug, device, or diagnostic is sold on the market. Based on terms approved in 2015, companies share a percentage of all product or service returns until four times the amount of their grant money is paid to Texas. After that, the company continues to pay Texas a 0.5% royalty payment.



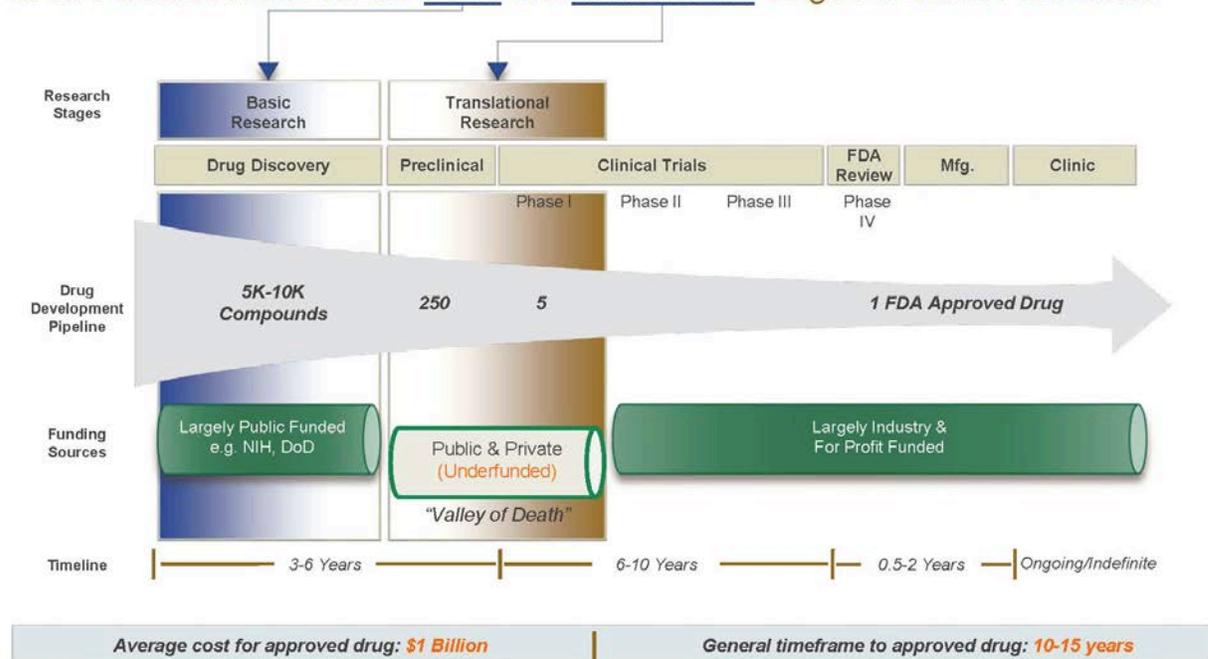
## CPRIT's Product Development Research grants accelerate the translational research and development of drugs, devices, and diagnostics to save the lives of cancer patients.

CPRIT's grants fill a critical funding gap between university-based research and later-stage investments by venture capital firms and pharmaceutical companies.

- CPRIT grants help fund the early studies, e.g., animal, Phase I and II clinical trials, which translate the promising research results into practical applications in humans. These early studies are necessary to show that the drug will work in patients.
- Because of the significant amount of money to which drug companies and venture capitalists have access, they are crucial in the drug development process. However, most venture capital and pharmaceutical investments are made *after* a promising drug shows signs it may work on patients, e.g., after Phase I clinical trials.
- Without CPRIT's grants to bridge the funding gap between university research and Phase II clinical trials, promising ideas to treat cancer could end up in what the life sciences community calls the "valley of death"—the place innovative ideas die for lack of funding. If a drug cannot make it through the valley of death, the potential benefits to patients will never be realized.

### CPRIT's Unique Role in Fighting Cancer

CPRIT awards focus on the basic and translational stages of cancer research.



# PRODUCT DEVELOPMENT PEER REVIEW PROCESS



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

<b>STEP 1</b> Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
<b>STEP 2</b> Applying Online	Applicants submit proposals using CPRIT's online application receipt system ( <a href="http://www.cpritgrants.org">www.cpritgrants.org</a> ). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and only for the grant mechanism under which the grant application was submitted.
<b>STEP 3</b> Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
<b>STEP 4</b> Reviewer Conflict of Interest (COI) Identification	Experts and advocates in development of products related to cancer research are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee (OC). The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers identify which applications match their area of expertise and flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
<b>STEP 5</b> Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process.
<b>STEP 6</b> Individual Evaluation and Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three or four) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
<b>STEP 7</b> Panel Discussion	The full peer review panel (12-15 reviewers) meets by teleconference and discusses the applications. After discussion, the primary reviewers may adjust their initial scores. The primary reviewers' individual overall scores are then averaged to provide an overall evaluation score for the application; the score and a summary statement of the reviewers' comments are generated for each application that does not move forward for further review. A reviewer with a conflict of interest for an application recuses themselves from the discussion and scoring of that application.
<b>STEP 8</b> In Person Presentations	Applicants with sufficiently positive scores after the panel discussion are invited to present their proposal to the full review panel and answer reviewer questions. Following the presentation, the reviewers discuss the application and all reviewers individually submit an overall score for the application. The individual overall scores are then averaged to provide a final overall evaluation score for the application; the score and a summary statement of the reviewers' comments are provided to each applicant. A reviewer with a conflict of interest for an application recuses themselves from the discussion and scoring of that application.
<b>STEP 9</b> Due Diligence Review	The applications that score sufficiently well after the in-person presentation undergo due diligence review conducted by outside contractors hired by CPRIT and overseen by the Chief Product Development Officer. Due diligence involves an in-depth evaluation of the proposal's underlying intellectual property, clinical trial design, regulatory affairs, manufacturability of product, marketing, etc. The due diligence reports are provided to the primary reviewers and the Product Development Review Council for their consideration.
<b>STEP 10</b> Review Council Recommendation	Following a discussion of the due diligence reports, the Review Council conducts a programmatic review and decides which applications should be recommended for CPRIT grant funding. Criteria considered during programmatic review are spelled out in the RFA. All Product Development applications recommended for grant funding are numerically ranked by the Review Council and submitted to the Program Integration Committee (PIC). The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO (as Chair of the PIC) and the OC. Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
<b>STEP 11</b> Program Integration Committee (PIC) Review	The PIC considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
<b>STEP 12</b> Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the OC members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
<b>STEP 13</b> Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements, including revenue sharing terms and agreed upon milestones.



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# CPRIT's Product Development Application Pedigrees

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2014  
 CYCLE 1  
 PROGRAM Product Development  
 AWARD MECHANISM  
 APPLICATION ID  
 APPLICATION TITLE  
 APPLICANT NAME  
 ORGANIZATION  
 PANEL NAME

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	05/12/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	05/12/14
	CPRIT Application Receipt System (CARS) closed	01/31/14	05/12/14
	Date application submitted	01/30/14	05/12/14
	Method of submission	CARS	05/12/14
	Within receipt period	YES	05/12/14
	Appeal to submit application after CARS closed	N/A	05/12/14
	Appeal for late application submission accepted	N/A	05/12/14
2. Receipt, Referral, and Assignment	Submission of application fee	YES	05/12/14
	Administrative review notification	N/A	05/12/14
	Donation(s) made to CPRIT/foundation	NO	05/12/14
	Assigned to primary reviewers	02/14/14	05/12/14
	Applicant notified of review panel assignment	02/26/14	05/12/14
	Primary Reviewer 1 COI signed	02/11/14	05/12/14
	Primary Reviewer 2 COI signed	02/19/14	05/12/14
	Primary Reviewer 3 COI signed	02/11/14	05/12/14
3. Peer Review: Screening Teleconference	Primary (Advocate) Reviewer 4 COI signed	02/11/14	05/12/14
	Primary (Advocate) Reviewer 5 COI signed	02/11/14	05/12/14
	Primary Reviewer 1 critique submitted	02/25/14	05/12/14
	Primary Reviewer 2 critique submitted	02/22/14	05/12/14
	Primary Reviewer 3 critique submitted	02/26/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
	Peer Review: Screening Teleconference	02/28/14	05/12/14
4. Peer Review: On-Site Meeting	Post-Screening Teleconference score report	03/04/14	05/12/14
	Post review statements signed	04/06/14	05/12/14
	Third Party Observer Report	02/28/14	05/12/14
	Recommended for On-Site Meeting	YES	05/12/14
	Primary (Advocate) Reviewer 4 critique submitted	03/24/14	05/12/14
	Primary (Advocate) Reviewer 5 critique submitted	03/25/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
5. Due Diligence and IP Review	Peer Review: On-Site Meeting	03/31/14 - 04/01/14	05/12/14
	Post review statements signed	04/01/14	05/12/14
	Third Party Observer Report	04/01/14	05/12/14
	Score report delivered to CPDO	04/08/14	05/12/14
	Recommended for due diligence and IP review	YES	05/12/14
	Final due diligence review submitted to PDRC	06/12/14	07/09/14
	Intellectual Property conflict check	04/08/14	07/09/14
	Final intellectual property review submitted	06/24/14	07/09/14
6. Final PDRC Recommendation	COI indicated by PDRC member	NONE	07/17/14
	COI recused from participation	N/A	07/17/14
	Due Diligence Evaluation Meeting / PDRC Meeting	06/27/14	07/17/14
	Third Party Observer Report	07/07/14	07/17/14
	Recommended for grant award	YES	07/17/14
7. PIC Review	PDRC Chair Notification to PIC and OC	06/30/14	07/17/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
8. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	08/04/14	09/10/14
	COI indicated by Oversight Committee member	NONE	09/10/14
	COI recused from participation	N/A	09/10/14
	Donation(s) made to CPRIT/foundation	NO	09/10/14
	Presented to CPRIT Oversight Committee	08/20/14	09/10/14
	Award approved by Oversight Committee	YES	09/10/14
	Authority to advance funds requested	YES	09/10/14
Advance authority approved by Oversight Committee	YES	09/10/14	



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# CPRIT Product Development Research Program

## Goals

- To improve patient care through expedited innovation and product development
- To foster economic development in Texas' emerging life sciences industry and the creation of high-quality new jobs in this state
- To provide a direct return, through intellectual property and revenue sharing, on the investments made by Texans

## Product Development Portfolio

## Grants

### Product Development Research Grants to date

- 45 grants announced totaling \$284 million (25 grants to companies and 20 Early Translational Research Awards to universities)
- \$44 million total grant amount expended to date
- Over \$360 million invested in R&D with matching funds
- Over \$900 million follow-on capital raised
- 260 expected number of jobs

(as of April 27, 2015)



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## Summary of CPRIT Product Development Research Contracts

	Grantee Organization (City)	Technology and Significance	Total Contract Obligation (MM)	Amount Spent to date (MM)	Follow-on Capital Post Award (MM)	Maximum Potential Return to CPRIT (MM)	Estimated Jobs at Company Build out
ACTIVE AWARDS	Mirna Therapeutics, Inc. (Austin)	<u>Therapeutic</u> : Clinical development of this mimic of the micro RNA tumor suppressor, miR-34, may enable the treatment of liver, colon, breast, prostate, and lung cancer.	\$10.30	\$10.30	\$53.20	\$20.59	20
	Rules-Based Medicine (Austin)	<u>Diagnostic</u> : Discovery and use of biomarkers in cancer to assist research and improve early detection.	\$3.02	\$2.45	\$81.00	no limit	10
	Bellicum Pharmaceuticals, Inc. (Houston)	<u>Therapeutic</u> : Cancer fighting T-cells are engineered with a "turn off" gene that can be activated in the case of Graft vs. Host Disease. Bellicum recently closed C-round financing for \$55 MM.	\$5.68	\$4.64	\$129.00 + \$140.60 at IPO	\$11.36	30
	Molecular Templates, Inc. (Georgetown)	<u>Therapeutic</u> : A highly toxic protein is joined to a CD20 targeting molecule to create a new and more effective leukemia and lymphoma treatment. Company received an IND to begin Phase I trials on 9-10-14.	\$10.60	\$3.85	\$19.00	\$21.20	12
	Pulmotect, Inc. (Houston)	<u>Therapeutic</u> : A combination of two TLR agonists stimulate the lung's innate immune system to prevent pneumonia in immunocompromised cancer patients.	\$7.13	\$2.49	\$3.65	no limit	15



## Summary of CPRIT Product Development Research Contracts

	Grantee Organization (City)	Technology and Significance	Total Contract Obligation (MM)	Amount Spent to date (MM)	Follow-on Capital Post Award (MM)	Maximum Potential Return to CPRIT (MM)	Estimated Jobs at Company Build out
ACTIVE AWARDS	Asuragen, Inc. (Austin)	<u>Diagnostic</u> : Next generation sequencing to provide mutation profiling to discover cancer-linked genomic variants for clinical research, drug development and improved care for cancer patients.	\$6.84	\$3.28	\$7.50	\$13.67	10
	Cell Medica (Houston)	<u>Therapeutic</u> : Patient T-cells are removed from the body, activated and expanded in number, and then reintroduced to attack lymphomas associated with Epstein Barr virus.	\$15.57	\$4.67	\$101.00	No Limit	20
	DNAtrix, Inc. (Houston)	<u>Therapeutic</u> : Development of an oncolytic adenovirus for the treatment of glioblastoma	\$10.81	\$1.01	\$20.00	\$64.8	10
	ESSA Pharma, Inc. (Houston)	<u>Therapeutic</u> : Blocking the androgen receptor overcomes hormone-therapy resistance in prostate cancer	\$12.00	\$0.28	\$12.00	\$58.4	15
	CerRx, Inc. (Lubbock)	<u>Therapeutic</u> : Compounds to cause overproduction of toxic ceramides in cancer cells	\$6.00	\$0.17	\$2.40	\$25.2	10
	Kalon Biotherapeutics (College Station)	<u>Therapeutic</u> : Formation of The Texas Cancer Therapeutics Process Development Lab	\$7.90	\$0.00	\$12.50 Acquired by Fuji for undisclosed amount	\$8.14	25



## Summary of CPRIT Product Development Research Contracts

	Grantee Organization (City)	Technology and Significance	Total Contract Obligation (MM)	Amount Spent to date (MM)	Follow-on Capital Post Award (MM)	Maximum Potential Return to CPRIT (MM)	Estimated Jobs at Company Build out
IN NEGOTIATION	Beta Cat Pharmaceuticals (Dallas)	<u>Therapeutic</u> : Development of an inhibitor of the beta catenin pathway in colorectal cancer	\$15.91	\$0.00	N/A	\$63.64 + 0.5% continuing revenue share	15
	AERase, Inc. (Austin)	<u>Therapeutic</u> : Depletion of an amino acid necessary for cancer cells causes cancer cell starvation and death	\$19.81	\$0.00	\$44.0	\$79.24 + 0.5% continuing revenue share	15
	Mirna Therapeutics, Inc. (Austin)	<u>Therapeutic</u> : Testing and developing previously developed lead compound in combination with other therapeutics	\$25.15	\$0.00	N/A	\$100.6 + 0.5% continuing revenue share	5
	Curtana Pharmaceuticals (Austin)	<u>Therapeutic</u> : Development of targeted small molecules for the treatment of brain cancers	\$7.58	\$0.00	N/A	\$30.32 + 0.5% continuing revenue share	15
	OncoNano Medicine (Dallas)	<u>Device</u> : Method for visualizing tumor cells during surgical resection	\$6.00	\$0.00	N/A	\$24.0 + 0.5% continuing revenue share	15



## Summary of CPRIT Product Development Research Contracts

	Grantee Organization (City)	Technology and Significance	Total Contract Obligation (MM)	Amount Spent to date (MM)	Follow-on Capital Post Award (MM)	Maximum Potential Return to CPRIT (MM)	Estimated Jobs at Company Build out
IN NEGOTIATION	NanoTx Therapeutics (San Antonio)	<u>Therapeutic:</u> Radiolabeled lipid nanoparticles are delivered directly to the brain for the treatment of glioblastoma and possibly other cancers.	\$2.00	\$0.00	N/A	\$8.0 + 0.5% continuing revenue share	12
	Medicenna Therapeutics, Inc.	<u>Therapeutic:</u> An IL-4:Pseudomonas exotoxin fusion protein targets IL-4R positive glioblastoma. Administered directly into the brain.	\$14.14	\$0.00	N/A	\$56.56 + 0.5% continuing revenue share	15
	Immatics Biotechnologies (Houston)	<u>Therapeutic:</u> Cancer immunotherapy employing adoptive cellular therapy and actively personalized cancer vaccines.	\$19.65	\$0.00	N/A	\$78.6 + 0.5% continuing revenue share	50
	Armada Pharmaceuticals, Inc. (Houston)	<u>Therapeutic:</u> Antibody-drug conjugate targeting the epidermal growth factor receptor.	\$12.75	\$0.00	N/A	\$51.0 + 0.5% continuing revenue share	15



## Summary of CPRIT Product Development Research Contracts

	Grantee Organization (City)	Technology and Significance	Total Contract Obligation (MM)	Amount Spent to date (MM)	Follow-on Capital Post Award (MM)	Maximum Potential Return to CPRIT (MM)	Estimated Jobs at Company Build out
On Hold	Caliber Biotherapeutics (College Station)	<u>Therapeutic</u> : Development of a plant made, "biobetter" Rituxan® (anti-CD20) for treatment of leukemia and lymphoma.	\$12.81	\$1.26	N/A	--	7
Closed	InGeneron, Inc. (Houston)	<u>Diagnostic</u> : Enrichment Filter and Point-of-use Assay Platform for Detection of Circulating Tumor Cells	\$0.20	\$0.08	\$3.75	\$0.22	3
	Visualase, Inc. (Houston)	<u>Device</u> : A laser system for precision guided destruction of localized prostate cancer reduces side effects of incontinence and sexual dysfunction.	\$2.15	\$1.44	\$5.20 + \$105 acquisition by Medtronic	\$2.05 (paid 8/14)	5
	Apollo Endosurgery (Austin)	<u>Device</u> : Novel flexible surgical devices enable removal of early-stage lesions from the colon, esophagus, and stomach	\$5.00	\$5.00	\$152.60	\$10.00	12
Suspended	Peloton Therapeutics, Inc. (Dallas)	<u>Therapeutic</u> : Research and development of small molecule inhibitors of hypoxic signaling; selective antagonists of Wnt signaling; and a platform for whole genome siRNA profiling	\$11.04	\$3.20	\$18.00	--	N/A



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## Grant Connections to Texas Academic Institutions

GRANTEE ORGANIZATION (APPLICATION TYPE)	TECHNOLOGY AND SIGNIFICANCE	UNIVERSITY	COMPANY LOCATION	CONTRACT OBLIGATION (MM)	CONNECTION TO TEXAS ACADEMIC INSTITUTIONS
<b>AERase, Inc.</b> (Established Company Product Development Award)	<b>Therapeutic:</b> Depletion of an amino acid necessary for cancer cells causes cancer cell starvation and death	The University of Texas at Austin	Austin	\$19.81	Technology based on research of George Georgiou at UT Austin. Company currently housed at UT Austin Incubator Center.
<b>Asuragen, Inc.</b> (Company Commercialization Award)	<b>Diagnostic:</b> Next generation sequencing will provide mutation profiling to discover cancer-linked genomic variants for clinical research, drug development and to improve care for cancer patients	The University of Texas M.D. Anderson Cancer Center	Austin	\$6.84	Currently conducting clinical trials at MD Anderson.
<b>Armada Pharmaceuticals, Inc.</b> (New Company Award)	<b>Therapeutic:</b> Antibody-drug conjugate targeting the epidermal growth factor receptor	The University of Texas M.D. Anderson Cancer Center	Houston	\$12.75	Clinical trials anticipated to be conducted at MD Anderson.
<b>Bellicum Pharmaceuticals, Inc.</b> (Company Commercialization Award)	<b>Therapeutic:</b> Cancer fighting T-cells are engineered with a "turn off" gene that can be activated in the case of Graft vs. Host Disease. Bellicum recently closed C-round financing for \$55 MM	The University of Texas M.D. Anderson Cancer Center	Houston	\$5.68	Clinical trials conducted at MD Anderson.
<b>Caliber Biotherapeutics</b> (Company Commercialization Award)	<b>Therapeutic:</b> Development of a plant made, "biobetter" Rituxan® (anti-CD20) for treatment of leukemia and lymphoma.	Texas A&M University	College Station	\$12.81	Spinoff company related to Texas A&M.
<b>DNatrix, Inc.</b> (Company Commercialization Award)	<b>Therapeutic:</b> Development of an oncolytic adenovirus for the treatment of glioblastoma.	The University of Texas M.D. Anderson Cancer Center	Houston	\$10.81	Clinical trials anticipated to be conducted at MD Anderson.
<b>Immatics Biotechnologies</b> (New Company Award)	<b>Therapeutic:</b> Cancer immunotherapy employing adoptive cellular therapy and actively personalized cancer vaccines.	The University of Texas M.D. Anderson Cancer Center	Houston	\$19.65	Will sub-contract all pre-clinical and clinical tasks to MD Anderson. Will perform bulk of clinical trials at MD Anderson.
<b>Kalon Biotherapeutics</b> (Company Formation Award)	<b>Therapeutic:</b> Formation of The Texas Cancer Therapeutics Process Development Lab.	Texas A&M University and The University of Texas M.D. Anderson Cancer Center	College Station	\$7.90	Research conducted at Texas A&M. Clinical trials conducted at MD Anderson.
<b>Medicenna Therapeutics, Inc.</b> (New Company Award)	<b>Therapeutic:</b> An IL-4:Pseudomonas exotoxin fusion protein targets IL-4R positive glioblastoma. Administered directly into the brain.	Texas A&M University	College Station	\$14.14	Company plans clinical trials in Texas for further development of its lead compound. Entered into development and manufacturing with Kalon in College Station.
<b>Mirna Therapeutics, Inc.</b> (Company Commercialization Award)	<b>Therapeutic:</b> Clinical development of this mimic of the micro RNA tumor suppressor, miR-34, may enable the treatment of liver, colon, breast, prostate, and lung cancer.	The University of Texas Health Science Center at San Antonio, The University of Texas Southwestern Medical Center and The University of Texas M.D. Anderson Cancer Center	Austin	\$10.30	Currently conducting clinical trials at UTHSC-San Antonio, UTSW in Dallas and MD Anderson in Houston.
<b>Mirna Therapeutics, Inc.</b> (Established Company Product Development Award)	<b>Therapeutic:</b> Testing and development of their lead compound in combination with other therapeutics.	The University of Texas Health Science Center at San Antonio, The University of Texas Southwestern Medical Center and The University of Texas M.D. Anderson Cancer Center	Austin	\$25.15	Currently conducting clinical trials at UTHSC-San Antonio, UTSW - Dallas and MD Anderson in Houston.
<b>Molecular Templates, Inc.</b> (Company Commercialization Award)	<b>Therapeutic:</b> A highly toxic protein is joined to a CD20 targeting molecule to create a new and more effective leukemia and lymphoma therapeutic.	The University of Texas M.D. Anderson Cancer Center	Georgetown	\$10.60	Launched clinical trials at MD Anderson in March, 2015.
<b>NanoTx Therapeutics</b> (New Company Award)	<b>Therapeutic:</b> Radiolabeled lipid nanoparticles are delivered directly to the brain for the treatment of glioblastoma and possibly other cancers.	The University of Texas Health Science Center at San Antonio	San Antonio	\$2.00	Licensed relevant technology from UT system. Headquartered in San Antonio; working to develop its lead compound product at Cancer Therapy and Research Center in San Antonio.
<b>OncoNano Medicine</b> (New Company Product Development Award)	<b>Device:</b> Method for visualizing tumor cells during surgical resection.	The University of Texas Southwestern Medical Center and The University of Texas M.D. Anderson Cancer Center	Dallas	\$6.00	Spinoff company from UTSW. Technology licensed from UT system. Scientific founders are UTSW Medical Center faculty. Company plans to run clinical trials at UTSW, MD Anderson, and Methodist Hospital.
<b>Peloton Therapeutics, Inc.</b> (Company Recruitment, Relocation, and Formation; suspended)	<b>Therapeutic:</b> Research and development of small molecule inhibitors of hypoxic signaling; selective antagonists of Wnt signaling; and a platform for whole genome siRNA profiling.	The University of Texas Southwestern Medical Center	Dallas	\$11.04	Principal Investigator is a faculty member and the company was incubated at UTSW.
<b>Pulmotect, Inc.</b> (Company Formation Award)	<b>Therapeutic:</b> A combination of two TLR agonists stimulate the lung's innate immune system to prevent pneumonia in immunocompromised cancer patients.	Texas A&M University, Baylor College of Medicine and The University of Texas M.D. Anderson Cancer Center	Houston	\$7.13	Technology developed in partnership with MD Anderson, Texas A&M and Baylor College of Medicine.



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## CPRIT's Product Development Review Council Member Biographies

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**Jack Geltosky, Ph.D., Chair of the Product Development Review Council**  
Managing Director, JEG and Associates, LLC

Jack has over 30 years of experience in the pharmaceutical industry, evenly split between R&D and licensing.

Jack was the Senior Vice President of Business Development for Arizona Technology Enterprises (AZTE), the technology transfer arm of Arizona State University, from 2007 to June of 2011. He now serves as a Senior Consultant to AZTE.

Jack served on the Board of Directors of Enzon Pharmaceuticals from 2008-2009 and is currently on the Board of Protox Therapeutics.

From 2002-2007, Jack was Vice President of External Science, Technology and Licensing at Bristol Myers Squibb. There he was responsible for the acquisition and licensing of compounds, R&D technologies and intellectual property to support the company's drug discovery and development efforts. In this role, Jack and his team identified, evaluated, and coordinated due diligence activities on potential in- and out-licensing candidates in pre-clinical and clinical development, across all therapeutic areas. Jack's team consisted of 15 licensing professionals.

Prior to joining BMS, Jack was President and Chief Executive Officer of Message Pharmaceuticals, a privately held biotechnology company focused on the discovery of drugs active on RNA. Previously he worked for SmithKline Beecham as Vice President, Scientific Licensing. He also held several other research and development roles of increasing responsibility with Johnson & Johnson, including Senior Director of Research for the Robert Wood Johnson Pharmaceutical Research Institute. Jack began his career as a research scientist at E.I. DuPont.

Jack holds a B.S. in chemistry from Memphis State University and a Ph.D. in biochemistry from the California Institute of Technology.





**David Shoemaker, Ph.D., Member - Product Development Review Council**

Senior Vice President, Research and Development, Rho, Inc.

David is currently responsible for developing integrated product development strategies for products ranging from discovery through market approval. David serves as an advisor to multidisciplinary program teams, contributing regulatory perspectives on clinical, preclinical, and chemistry, manufacturing and controls development decisions.

David has participated in the development of the regulatory strategy for programs involving central nervous system products, blood products, oncology therapeutics and

vaccines, gene and stem cell products, immunomodulators, cardiovascular therapeutics, and metabolic and endocrine therapeutics. He has experience in the preparation and filing of all types of regulatory submissions, from regulatory authority meeting briefing packages to INDs, IMPDs, CTAs, NDAs/BLAs and MAAs. He has moderated dozens of regulatory authority meetings and negotiated the release of several products from regulatory clinical hold.

David's primary areas of expertise include the design of preclinical and clinical study protocols and the integrated regulatory strategy for the development of novel drug and biological products; however, he is also well-versed in the development of products for 505(b)(2) and biosimilar marketing applications



**Kapil Dhingra, M.D., Member - Product Development Review Council**

Consultant, KAPital Consulting, LLC

Dr. Dhingra founded KAPital Consulting, LLC, in 2008, a company dedicated to helping biotechnology, pharmaceutical and diagnostic companies realize the clinical and commercial advances in oncology.

From 1999 to 2008, Dr. Dhingra served in positions of increasing responsibility at Hoffmann-La Roche, including Vice President, Head, Oncology Disease Biology Leadership Team, and Head, Oncology Clinical Development. Prior to joining Roche, he worked in the oncology clinical development group at Eli Lilly and Company. From 1989 to 1996, he was a faculty member at The University of Texas M.D. Anderson Cancer Center where he led a successful laboratory as well as clinical research program. Throughout his industry career, Dr. Dhingra maintained an active faculty appointment, at Indiana University School of Medicine from 1997 to 1999, and, more recently, at Memorial Sloan Kettering Cancer Center in New York from 2000 to 2008. Dr. Dhingra holds an M.B.,B.S. (equivalent to US M.D.) degree from the All India Institute of Medical Sciences (AIIMS), and has performed postgraduate work at the AIIMS, the Lincoln Medical and Mental Health Center (New York Medical College), Bronx NY and Emory University School of Medicine, Atlanta GA. He is Board-certified in Internal Medicine and Medical Oncology. Dr. Dhingra is currently Chairman of Board of Exosome Diagnostics and a member of Board of Directors of Epitherapeutics as well as Advanced Accelerator Applications. In addition, he is an advisor to several biotechnology and



pharmaceutical companies and healthcare organizations. He is also a member of the NCI Experimental Therapeutics panel and a member of the New Drug Advisory Committee of the EORTC. He has previously served on the Boards of several successful biotech companies, including Biovex, Micromet, Algeta, and YM Biosciences, which were acquired by major pharmaceutical companies.



**Roy Cosan, B.B.A. , Member - Product Development Review Council**  
Managing Director, Fjord Ventures

Roy Cosan is a Managing Director of Fjord Ventures. Roy's experience includes 32 years with Johnson and Johnson. He was Vice President of New Product Development at Janssen Pharmaceutica where he launched Risperdal and Reminly. Roy was also a Vice President with the Johnson & Johnson Development Corp., the venture capital arm of J&J where he invested in 19 companies and held 11 board of director seats. Roy helped build a virtual R&D capability within J&J Pharma.



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## CPRIT's Product Development Peer Review Panel Members

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### **Alex Adjei, M.D., Ph.D.**

Senior Vice President of Clinical Research Professor and Chair, Department of Medicine The Katherine Anne Gioia Chair in Cancer Medicine Roswell Park Cancer Institute

Alex joined the faculty of Roswell Park Cancer Institute (RPCI) in 2006 as Senior Vice President of Clinical Research and Chair of the Department of Medicine.

Alex is responsible for expanding the Department's phase I and Thoracic Oncology programs and strives to enhance existing programs and establish new clinical and research initiatives.

Alex is a distinguished national leader in translational research, drug development and thoracic oncology. He comes to RPCI from the Mayo College of Medicine, Rochester, MN, where he served as Professor of Oncology and led highly successful thoracic oncology and Phase I clinical research programs.

Alex earned his medical degree from the University of Ghana Medical School in Legon. He obtained a doctorate degree in pharmacology at the University of Alberta in Edmonton, Canada. Alex completed residency training at Howard University, Washington, DC, and clinical and research fellowships in oncology at Johns Hopkins School of Medicine, Baltimore, MD. He is a Diplomate of the American Board of Internal Medicine.

Alex's research is focused on assessing the toxicity, pharmacology and initial activity of novel agents for the therapy of solid tumors and developing biomarkers of drug effects. His laboratory studies focus on elucidating mechanisms of action and resistance of novel agents that inhibit cell signaling. He also conducts phase II clinical trials of novel agents in lung cancer.

Alex is an active member of numerous professional organizations. As a member of the American Association for Cancer Research (AACR), he has served as Chair of the Minorities in Cancer Research Council; Co-Chair of the AACR's 2005 Annual Meeting and currently is Co-Chair of the 2007 AACR Annual Meeting.

Alex also has served on many committees for the National Cancer Institute. He is Group Vice-Chair of the North Central Cancer Treatment Group (NCCTG) and Chair of the NCCTG Lung Cancer Committee. He was a member of the Lung Cancer Progress Review Group in 2000 and the Lung Cancer Concept Evaluating Panel from 1999-2002. He is a member of the Clinical Research Review Committee Study Section of the National Center for Research Resources for the National Institutes of Health, and the Investigational Drug Steering Committee, for which he co-chairs the Clinical Trials Design Task Force.

Alex has authored or co-authored more than 200 journal articles, abstracts and book chapters. He is a Senior Editor of Molecular Cancer Therapeutics; Associate Editor of the American Journal of Clinical Oncology and Current Drug Targets, and a member of the editorial boards for



Investigational New Drugs, Journal of Clinical Oncology, Cancer Chemotherapy and Pharmacology, Clinical Lung Cancer, Medicinal Chemistry Reviews and Update on Cancer Therapeutics.



**Michelle Arkin, Ph.D.**

Associate Adjunct Professor, University of California, San Francisco  
Pharmaceutical Chemistry

Michelle Arkin is an Associate Professor in Pharmaceutical Chemistry and the Associate Director of Biology at the Small Molecule Discovery Center at UCSF. Michelle's research interests include developing biological tools and drug leads for orphan and neglected diseases and designing compounds to modulate the function of allosterically regulated enzymes and protein-protein interactions (PPI). As associate director of the SMDC, Michelle oversees the high-throughput screening operation and collaborates with many academic and pharmaceutical laboratories to tackle challenging problems in drug discovery. Michelle earned her PhD in chemistry at Caltech and then held a Daymon Runyon postdoctoral fellowship at Genentech. She was among the first scientists at Sunesis Pharmaceuticals, where she developed inhibitors of PPI, including SAR1118, currently in phase 3 trials for dry-eye at SARcode. From 2005 to 2007, she was the Associate Director of Cell Biology at Sunesis and led the translational science team for Vosaroxin, an anti-cancer agent in phase 3 clinical trials.



**Gabriel Cipau, Ph.D., M.B.A., M.S.**

President, Key Healthcare Partners, Inc.

Gabriel has spent 42 years in the pharmaceutical and biotechnology industry. He joined Burroughs Wellcome Co. as a research scientist in 1970 and held positions of increasing responsibility in R&D and manufacturing, including Director of Technical R&D and Senior Vice president of Operations. In these capacities, Gabriel was involved in the development and production of 23 new cardiovascular, antibacterial and antiviral pharmaceutical products.

In 1993 he was appointed President and CEO of Wellcome Japan and a member of the Board of Directors of Wellcome PLC and of Wellcome Foundation Ltd based in UK.

Gabriel joined Copley Pharmaceuticals as President and CEO in 1995 and later on was a founder, CEO and President of Catalytica Pharmaceuticals, Biolex and PhaseBio Pharmaceuticals.

Following his retirement in 2006, Gabriel established Key Healthcare Inc. a consulting company providing services for investors and companies involved in the pharmaceutical and biotechnology areas. He is a member of the Board of Directors of several companies operating in this field.





**Neil J Clendeninn M.D., Ph.D.**

President, CANAID, Inc.

Dr. Clendeninn has over 20 years' experience in the pharmaceutical/biotech industry. He was recently the VP of Clinical for Agouron Pharmaceuticals, of La Jolla, CA. He developed the AIDS protease inhibitor Viracept, which was approved in record time of 36 months. He previously worked for Burroughs Wellcome, Research Triangle Park, NC where he was head of Clinical Oncology.

Dr. Clendeninn received his BA (Biology and Chemistry) from Wesleyan University, Middletown, CT and his MD and PhD (Pharmacology) from New York University, NY. He trained at NCI in Oncology and specialized in new drug development.

He has served on a number of Boards including Oncogenex Technologies, Vancouver, Canada, and the Board of Scientific Advisors for NCI. He also consults for a number of biotech companies, CROs and investor companies. He is the author of over 150 papers, abstracts and textbooks.

He is currently heading a medical practice team developing early palliative care on Kauai, HI.



**Adam R. Craig, M.D., Ph.D., M.B.A**

Executive Vice President, Development and Chief Medical Officer

Adam R. Craig, M.D., Ph.D., M.B.A., was appointed Chief Medical Officer of Sunesis in February 2012. Prior to Sunesis, Dr. Craig served as Chief Medical Officer at ChemGenex Pharmaceuticals, where he led the development program for omacetaxine, an investigational treatment for chronic myeloid leukemia, including serving as the lead presenter and moderator for a 2011 Oncologic Drug Advisory Committee (ODAC) presentation. ChemGenex was acquired by Cephalon/Teva for \$225M in 2011. Before joining ChemGenex in 2007, he was founding Chief Medical Officer at Innovive Pharmaceuticals, Inc., a hematology- focused company. Prior to joining Innovive, Dr. Craig held positions of increasing responsibility at ArQule Inc., Ilex Oncology Inc., and Antisoma plc. Dr. Craig received his medical qualifications from the University of London, a Ph.D. in molecular medicine from the University of Leeds, and an M.B.A. from the Open Business School in the United Kingdom. Dr. Craig is a member of the Royal College of Pediatrics and Child Health Physicians (UK) and undertook post- graduate training in pediatrics and pediatric oncology. He also currently serves as a member of the Commercialization Review Council for the Cancer Prevention Research Institute of Texas, a \$3 billion fund for groundbreaking cancer research and prevention programs and services.





**Raymond DuBois, M.D., Ph.D.**

Executive Director, The Biodesign Institute at Arizona State University

Raymond DuBois, MD, PhD, is the executive director of the Biodesign Institute at Arizona State University. Biodesign is a research institute engaged in addressing critical global challenges in health care, sustainability and security. In addition to his role at Biodesign, DuBois has joint ASU appointments as the Dalton Chair, School of Health Solutions; and Professor, Department of Chemistry and Biochemistry.

DuBois began his Biodesign Institute leadership role in December 2012. In addition to his ASU responsibilities, his appointment includes co- leadership of the Cancer Prevention Program at the Mayo Clinic, which has a hospital and clinic, and is developing a medical school campus in the Phoenix area.

An internationally renowned expert in the molecular and genetic basis for colorectal cancer, DuBois maintains his own laboratory at Biodesign to examine the molecular mechanisms by which inflammatory mediators affect epithelial biology, the tumor microenvironment, carcinogenesis and development.

Prior to coming to ASU, DuBois was provost and executive vice president and professor of cancer medicine and cancer biology at the University of Texas MD Anderson Cancer Center in Houston. From 1998 to 2004, DuBois directed Vanderbilt's Division of Gastroenterology, Hepatology and Nutrition.

In the 1990s, DuBois and colleagues reported that colorectal tumors contained high levels of the enzyme cyclo- oxygenase- 2 (COX- 2). This enzyme is a key step in the production of pro-inflammatory mediators such as prostaglandin E2. The DuBois team was the first to show that colorectal cancers over- expressed COX- 2 and their research defined a series of critical molecular pathways involved in COX- 2 expression – namely, that blocking or inhibiting the COX- 2 enzyme would cause colorectal tumors to shrink. This work led to clinical trials and the treatment of precancerous polyps with Celebrex, an arthritis drug that selectively inhibits COX- 2.

During his career as a physician- scientist, DuBois has published 137 peer reviewed journal articles, 62 article reviews, 25 book chapters, and three books, the latest of which is entitled “Progress in Experimental Tumor Research.” DuBois is a co- inventor of a method to identify and prevent cellular genes necessary for viral growth and cellular genes that function as tumor suppressors in mammals.

DuBois' first two degrees were in biochemistry. He earned a bachelor's degree from Texas A&M University and a doctoral degree from the University of Texas Southwestern Medical Center at Dallas. DuBois obtained a medical degree from the University of Texas Health Science Center at San Antonio, followed by an Osler Medicine internship and residency, and a gastroenterology fellowship at the Johns Hopkins Hospital in Baltimore.





**James (Jim) E. Foley, Ph.D.**  
Managing Director, Aqua Partners LLC

Jim's career in the pharmaceutical industry began in 1977 at the Squibb Institute of Medical Research (E. R. Squibb and Sons). In 1989, he joined the Department of Licensing and Business Analysis at Squibb and relocated to Tokyo to further establish the company's worldwide pharmaceutical licensing activities in Japan and relationships with Japanese R&D-based pharmaceutical companies. Jim joined SmithKline Beecham's Worldwide Business Development Team in 1991 as Vice President and Director, Business Development-Japan/Asia, and remained based in Tokyo, representing the company's worldwide licensing interests in Japan, Asia, and Australia/New Zealand. He returned to the United States in 1995, where he continued his responsibilities based in Philadelphia. In 2002, Jim re-joined Bristol-Myers Squibb as Vice President, Business Development- Japan/International, focused on the identification of strategic R&D collaboration and product licensing opportunities from the Japan, Asia and Australia/New Zealand region. From April 2006 to February 2008, Jim was President and CEO of SMART Biosciences, an early-stage discovery biotechnology company focused on neurodegenerative diseases, particularly Alzheimer's disease. Jim joined Aqua Partners, a corporate and business development advisory firm focused on strategy development, licensing, M&A and finance for biotechnology and mid-tier pharma companies worldwide, with a special expertise in cross-border relationships and deal making.

Jim serves or has served on the Board of Trustees of St. Peter's School, Philadelphia, the Boards of Directors of SFJ Pharmaceuticals, Traxion (Baltimore), Sosei and Company (Tokyo), the Japan-America Society of Greater Philadelphia and New York Pharma Forum, and the Advisory Boards of the Haub School of Business (St. Joseph's University, Philadelphia), the Marshall School of Business Global BioBusiness Initiative (University of Southern California, Los Angeles), and Sc Capital I (University City Science Center, Philadelphia). Jim co-chairs the US-Japan Health Sciences Dialogue, an annual meeting held in Philadelphia addressing healthcare issues/solutions in the U.S. and Japan. A member of the Licensing Executives Society (LES), Jim was honored by the organization with the Frank Barnes Mentorship Award. He was designated a Certified Licensing Professional (CLP™) by LES in 2008. Jim holds a Ph.D. in Physiology from Thomas Jefferson University College of Graduate Studies. He received a B.A. in Biology and Chemistry from Rutgers University. He was a NIH Post-Doctoral Fellow from 1975 to 1977 in the Department of Pharmacology, Tulane University School of Medicine.



**Judy Fox**  
Consultant, FoxBiopharma, LLC

Judith A. Fox, Ph.D. is a consultant for the research and development of large and small molecule oncology therapeutics as founder of FoxBiopharma LLC, and also serves as Senior Vice President, Research & Development for Amphivena Therapeutics. Most recently, Dr. Fox was Vice President, Product & Preclinical Development at Sunesis Pharmaceuticals, where she led the vosaroxin program in acute myeloid leukemia through early to late stage clinical development. Previously, she was Senior Director in Translational Sciences at Chiron Corporation (now Novartis AG), supporting the development of the company's novel oncology compounds, and she established the Pharmacological Sciences Department at Genencor



International. Dr. Fox's industry career began at Genentech, Inc. where she contributed to the development of products such as Herceptin®, Xolair®, Raptiva® and Avastin®. Her career has focused on the translation of basic mechanistic understanding of promising drugs into coherent, evidence-based clinical development. Dr. Fox received her Ph.D. in Biological Chemistry from the Massachusetts Institute of Technology, where she serves on the Chemistry Visiting Committee, and an A.B. in Chemistry from Bryn Mawr College. She conducted postdoctoral research at The Rockefeller University.



**Darrick Fu**

Director of Business Operations, The Dermatology Center

Darrick Fu is currently Director of Business Operations at The Dermatology Center of Raleigh P.A., where he has profit and loss responsibility for a private medical practice. In this role, Mr. Fu has been implementing strategies that position a small business to meet the challenges of tomorrow's complicated healthcare environment.

Previously, Mr. Fu was Chief Product Development Officer at the Duke Human Vaccine Institute in Durham NC where he worked to translate discovery research into early, proof of concept, human trials in the field of HIV/AIDS vaccine discovery for a novel academic consortium by applying a virtual quasi-biotech model.

Prior to joining Duke, Mr. Fu was Vice President Scientific & Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA). At PhRMA, he led several industry wide strategic initiatives to improve the biopharmaceutical R&D business model in order to assure continued innovation in medicines. In this role, he managed a portfolio of industry activities aimed at modernizing the drug development process by developing innovative new tools in concert with regulatory authorities particularly the US FDA.

Under Mr. Fu's stewardship at PhRMA, a strategic effort was undertaken to identify and apply novel new businesses and mechanisms to address common critical R&D challenges. As result, Mr. Fu became PhRMA's principle architect and chief negotiator in the establishment and operational initiation of two major new public-private-partnerships; "The Biomarker Consortium" and the "Observational Medical Outcomes Partnership" both of which were the first novel mechanisms established joining major industry non-competitively with academia, and regulatory to conduct pre-competitive R&D that addresses critical challenges facing the drug development enterprise. Both these PPP's still stand and have spawned a generation of other consortia using a similar template.

Mr. Fu has over 20 years of industrial drug development experience in the biopharmaceutical industry principally with GSK. During his career at GSK Mr. Fu has held management positions in project management, development alliances, and licensing. At GSK Biologicals, in Rixensart Belgium, he led several successful new biopharmaceutical product development teams, including the development of Lymerix™ a vaccine against Lyme Disease from the pre-clinical phase through licensure in the USA, as well as the early and phase IIb POC development of Cervarix™ a vaccine that prevents cervical cancer. Mr. Fu has also served as consultant to the biotechnology and non-profit sectors on product development, business, and strategic issues.



Mr. Fu holds a B.S. degree in biochemistry from Carnegie Mellon University, and an M.B.A. from George Washington University.



**Phyllis Gardner, M.D., BIO**

Professor of Medicine; Partner (EWHV)  
Stanford University & Essex Woodlands Health Ventures

Phyllis Gardner has over 35 years of experience in academia, medicine and the healthcare industry. She began her professional career in 1984 at Stanford University, where she has held several positions including Senior Associate Dean for Education and Student Affairs and remains today as tenured Professor of Medicine and a member of the Academic Council Committee on Research. Her primary focus at Stanford today is as advisor to Stanford Students for Biodesign and course director of biopharmaceutical and medical innovation courses. From 1994 to 1998, she took a leave of absence as the Vice President of Research and Head of ALZA Technology Institute, a major drug delivery company. Phyllis currently serves on the Board of Fellows at Harvard Medical School and is a member of the Advisory Council on Education and the Campaign Steering Committee. She has conducted extensive research in cell biology and gene therapy, is widely published in the fields of cell biology and pharmacology, and has received numerous national awards and honors recognizing her academic and professional accomplishments.

Phyllis holds a Bachelor of Science degree from the University of Illinois and a Doctor of Medicine degree from Harvard Medical School. She trained in internal medicine at Massachusetts General Hospital, followed by Chief Residency at Stanford University Hospital and post-doctoral fellowships at Columbia University and University College London. In addition to her academic career, she is an adjunct partner at Essex Woodlands, a private equity company focused on the health science industry, where she has been affiliated for 15 years. She has served as the co-founder of three companies, as well as director of multiple private and public companies, the latter of which include Corium International and Revance Therapeutics, Inc.



**Stanton L. Gerson, M.D.**

Professor of Medicine, Oncology & Environmental Health Sciences, CWRU,  
Case Western Reserve University

Stanton [Stan] L. Gerson M.D. is the Asa and Patricia Shiverick - Jane Shiverick (Tripp) Professor of Hematological Oncology, Director NCI designated Case Comprehensive Cancer Center, Director of the Seidman Cancer Center, and founding director of the National Center for Regenerative Medicine in Cleveland.

Dr. Gerson discovered that the MGMT DNA repair gene protected multiple organs from alkylating agent induced malignancies. Later, this discovery was also the basis for development of a drug to block MGMT for cancer treatment, and an MGMT hematopoietic stem cell gene therapy approach, currently used in glioma, to protect marrow from chemotherapy. In



his stem cell research, he developed mesenchymal stem cells (MSCs) as a therapeutic infusion for blood stem cell transplantation. Others went on to receive International Regulatory approval for use of MSCs in GVHD therapy. Dr. Gerson also discovered the use of methoxyamine (TRC102) as a drug to block base excision repair, and identified its potentiation of anti-cancer efficacy when used in combination with either temozolomide, fludarabine or pemetrexed. Each of these is now in cancer clinical trial and is being evaluated at NCI-CTEP. Finally, Dr. Gerson has developed transgenic mouse models that examine the role of critical DNA repair genes (MGMT, MMR genes, NHEJ genes, and Homologous Recombination genes) in the stability of stem cell populations over the lifetime of the animal, and is studying similar processes in humans. These studies may predict stem cell diseases of aging and cancer. His research has generated 17 patents in the area of gene therapy and cancer drug development that have been licensed to 3 companies. In 2012 he was the recipient of the CWRU Medal for Excellence in Health Science Innovation Award. In 2013, CWRU honored him with the Distinguished University Professor designation.

Dr. Gerson serves on the NCI Board of Scientific Advisors and has chaired the FDA Advisory Board for Cell and Gene Therapy. Since 2003, he has been Director of the National Center of Regenerative Medicine and the NCI designated Case Comprehensive Cancer Center involve coordinating research throughout the medical centers in Cleveland – University Hospitals, Cleveland Clinic and Case Western Reserve University. At University Hospitals, he led effort to bring cancer care under one roof in the Seidman Cancer Center hospital that opened in June 2011.



**Mara Ginsberg, Esq.**

President, To Life!

*Advocate Reviewer*

Mara Ginsberg, Esq. is a partner in the Albany law firm of Hinman Straub, P.C. where she has both a legal and legislative practice including areas relating to health care and Medicaid compliance, procurement and technology. Prior to joining Hinman Straub, Mara served as Vice President of Government Affairs for AmeriChoice of New York & United Healthcare of New York where she led legislative and regulatory health policy for this

Medicaid managed-care company. Mara served for over 25 years in New York State Government as Counsel and Deputy Director at various State agencies involved with technology including broadband and cyber security. Mara also served as a New York State Assistant Attorney General.

Mara is the Founder and President of To Life! She founded To Life! in 1998 and this nonprofit organization in the Capital Region of New York now serves 10+ counties by providing comprehensive education programs and support services relating to breast cancer and women's health and wellness free of charge in non-clinical settings. To Life! has two offices and in addition to providing education forums, one-one mentoring for women, breast self-examination training, health and wellness programs, To Life! has boutiques where women can obtain breast prosthesis, mastectomy bras, hats, scarves and wigs. All programs and services are free of charge and To Life! is a provider for products with many insurance companies and never turns anyone



away even if they don't have insurance or other financial resources. Mara has several health policy affiliations:

- NYS Advisory Council for Breast and Cervical Cancer Education and Research
- Advisory Review Panel for Pesticide Information Release
- United States Department of Defense (Consumer Grant Reviewer)



**Gwen Harding-Peets, Ph.D.**

Regional Coordinator, SHARE: Self-Help for Women with Breast or Ovarian Cancer Regional Coordinator, Ovarian Cancer National Alliance's signature program, Survivors Teaching Students – Saving Women's Lives®  
*Advocate Reviewer*

Gwen Harding-Peets has a PhD in microbiology from the University of Texas at Austin. She joined Texaco, Inc. in 1989 as a Research Microbiologist evaluating means of using microbes to clean up spills and convert waste to more useful products. She moved into the IT department where she became very interested in knowledge management, but left corporate American in 2002 when Texaco merged with Chevron.

Gwen was diagnosed with Stage III C high grade serous ovarian cancer on February 7th, 2005. She has had one recurrence but has been NED since her last chemo in November 2008. Since her diagnosis, she has become very active in the ovarian cancer community. She is SHARE's Regional Coordinator for the Hudson Valley and volunteers on their ovarian cancer national helpline. She is the New York/New Jersey Regional Coordinator for the Ovarian Cancer National Alliance's signature program, Survivors Teaching Students – Saving Women's Lives®. She facilitates Support Connection's monthly toll-free telephone support group for women with ovarian cancer. She has been a research advocate and a DoD Ovarian Cancer Research Program consumer reviewer for a number of years.

In her spare time, she's a part time docent/educator at Locust Grove – the Samuel Morse historic site, photographs nature, and is a civil war living historian. But most of all enjoys every day that she shares with her family and her cats.



**Elaine V. Jones, Ph.D.**

Pfizer Venture Investments, Executive Director, Venture Capital

She is responsible for making and managing venture investments for Pfizer and currently manages the PVI investments in Aquinox Pharmaceuticals (Vancouver, British Columbia), Flexion Therapeutics (Boston, MA), Merus B.V. (Utrecht, The Netherlands), and NeuroTherapeutics Pharma (Chicago, IL). Elaine brings 10 years of venture capital experience and a strong background in research and product assessment, built on her significant experience in pharmaceutical drug discovery and business development to the PVI team.



Most recently, Elaine was a General Partner with the venture fund, EuclidSR Partners. There, she was responsible for the fund's investments in Acurian, Fluidigm, InnaPhase and Targacept.

Prior to joining ESR, Dr. Jones began her private equity career in 1999 at S.R. One, GlaxoSmithKline's venture fund, where she managed investments including Adolor, Avantium, Nucleonics, Scynexis and Vicuron. Previously, she served as Director of Scientific Licensing for SmithKline Beecham and was a research scientist in SmithKline Beecham Pharmaceutical R&D.

Dr. Jones is a graduate of Juniata College and received her Ph.D. in Microbiology from the University of Pittsburgh.



**James (Jim) F. Jordan, B.B.A., M.B.A.**

President, StraTactic, Inc.

James is an accomplished Fortune 20-level executive with strong experience in industry and consulting. Mr. Jordan is also a Distinguished Service Professor with Carnegie Mellon University's Heinz College and the Sr. Program Director of their Health Care and Biotechnology Masters Programs. As a recognized expert in market development and guiding the successful formation of entrepreneurial startup businesses in the Life Sciences Industry, Jim joined the Pittsburgh Life Sciences Greenhouse (PLSG) in 2005 and became Vice President and Chief Investment Officer in 2007. Prior to joining the PLSG, Jim served as Senior Vice President of a \$3.0 billion division of McKesson Corporation and Vice President, Marketing at Johnson & Johnson. He has held a range of management positions in sales and marketing, operations, supply chain, information technology, finance, and quality assurance with several Fortune 500 medical device companies including C.R. Bard, Inc. and Boston Scientific, Inc. Jim has leveraged this experience in several startup ventures and is active on several Boards of Directors.



**Michael S. Katz, MBA**

Co-Chair, Cancer Research Advocate Committee, ECOG-ACRIN Vice President, International Myeloma Foundation  
*Advocate Reviewer*

Mike is a 23 year survivor of multiple myeloma. He is a member of the Executive Board of the International Myeloma Foundation (IMF), Co-Chair of the ECOG-ACRIN Cancer Research Group's Executive Cancer Research Advocate Committee and a member of that group's Executive Committee, past chair of the National Cancer Institute's Director's Consumer Liaison Group (DCLG), a past-member of the National Cancer Institute's Myeloma Steering Committee, a Patient Consultant for the Food and Drug Administration (FDA), past member of the ASCO's Cancer Research Committee as well as past-chair the Association of Cancer Online Resources (ACOR.)

Mike is heavily involved in patient education and support and is broadly involved in publicly- and privately-funded cancer research efforts. He is a frequent speaker at cancer patient/family



seminars and medical conferences. Mike produces webcasts from national and international medical meetings that provide detailed information to the scientific and lay communities. He has also developed educational videos for potential participants in clinical trials.

Working through the ECOG-ACRIN Cancer Research Group, Mike was one of the leads in developing a trial that found superior survival with lower steroid doses and ultimately changed the global standard for use of high dose steroids in multiple myeloma. He also played a lead role in the IMF's web-based survey that confirmed the link between bisphosphonates and Osteonecrosis of the Jaw. He played a lead role in the development of the IMF's web site and its "Myeloma Manager™ Personal Care Assistant™," a software tool distributed free of charge to help patients and caregivers manage their personal medical data. Mike serves as a member of the Management Committee for the IMF's Bank on a Cure program. He has also played lead roles in web-based research on drug safety and quality of life issues.

Working with a fellow patient, June Brazil, Mike started the ACOR myeloma and amyloidosis listservs (online discussion groups), which now have over 2500 members. He also leads two in-person myeloma support groups in the New York Metropolitan area.

Mike has degrees in Electrical Engineering/Computer Science and Business from Columbia University. He worked for over 30 years at a major international management consulting firm, at which he served as a senior partner and member of the Board of Directors. He is Chairman and Chief Technology Officer of Expert Logic Systems and is a volunteer with the International Myeloma Foundation.



**Gerard (Gerry) Kennealey, M.D.**  
SVP & CMO, Oncolytics Biotech, Inc.

Gerry Kennealey is currently the SVP and Chief Medical Officer for Oncolytics Biotech, Inc., a publicly traded (ONCY) firm headquartered in Calgary, Alberta. He began his industry career in 1987 at AstraZeneca Pharmaceuticals where he was involved in the development of many products for breast and prostate cancer. He also lead the Expanded Access Program for Iressa® in lung cancer which enrolled >20,000 patients in the US and several thousand more abroad. He has also held executive positions at Eximias Pharmaceuticals, MGI Pharma, and Cephalon, Inc.

Gerry is a board certified medical oncologist and spent several years in private practice in Waterbury, CT prior to joining the pharmaceutical industry.



**Moira E. Lawrence, Ph.D.**  
Vice President, Alliance Management, Onconova Therapeutics

Moira has more than 15 years of experience in business development and technology commercialization. Prior to joining Onconova, she was Director of Oncology Business Development at Forest Laboratories. She also spent several years in business development at Bristol-Myers Squibb and technology commercialization at University of Maryland. Moira received her Ph.D. from University of Virginia in Cell Biology and Anatomy.





**Yueming Li, Ph.D.**

Professor of Molecular Pharmacology and Chemistry Memorial Sloan-Kettering Cancer Center

The main interests of my laboratory are to elucidate the mechanism of  $\gamma$ -secretase- dependent Notch signaling and amyloid precursor protein (APP) processing under physiological and pathological conditions and to develop target-based therapies.  $\gamma$ - Secretase represents a novel class of proteases that catalyze proteolysis of substrates within the transmembrane domain, an apparently hydrophobic environment, wherein water is required for peptide hydrolysis. Intramembranous proteases, including  $\gamma$ -secretase, site 2 proteases, rhomboids and signal peptide peptidase, play an essential role in many biological processes ranging from sterol regulation to development. Unraveling the intricacies of these enigmatic proteases is a formidable challenge that requires not only multi-disciplinary approaches, but also development of novel technologies that are suitable to study the structure and catalysis of membrane proteins. I have brought chemical biology into intramembranal proteolysis that significantly advances our understanding of  $\gamma$ -secretase and other proteases. We developed the first in vitro  $\gamma$ -secretase activity assay and made a groundbreaking discovery that  $\gamma$ -secretase activity is catalyzed by the presenilin containing macromolecular complex, providing a molecular basis to search for additional subunits. More significantly, my group has demonstrated that presenilin contains the active site of  $\gamma$ -secretase, revealing the first biochemical identity of  $\gamma$ -secretase using photoaffinity labeling approaches. Publication of this work in Nature was recognized as a “hot paper” by The Scientist, due to the large volume of citations. Furthermore, my lab has reconstituted  $\gamma$ -secretase and presenilinase using recombinant proteins and provided the final proof that presenilin is  $\gamma$ -secretase, which has offered a novel platform for studying the structure and function of  $\gamma$ -secretase at both molecular and atomic levels. This work on the reconstitution of  $\gamma$ -secretase published in PNAS was selected as one of the Alzheimer Research Forum’s 13 Top AD Trends in 2010. Recent clinical disappointment of  $\gamma$ -secretase inhibitor studies indicates that development of  $\gamma$ -secretase based therapy is an enormous challenge that requires a comprehensive understanding of the target. We have focused on development of  $\gamma$ -secretase modulators (GSMs) and elucidation of their mechanism of action using an integrated approach of chemical biology and proteomics. We have demonstrated that GSMs target  $\gamma$ -secretase and structurally distinct GSMs occupy different sites of  $\gamma$ -secretase, offering a molecular basis for drug combination studies.



**Ramona Lloyd, Ph.D.**

President & Principal Consultant, CYMREG CONSULTING

As a regulatory professional for over 20 years, Ramona has led or participated in the submission of numerous global investigational applications and successful marketing applications for small molecules, biologics and devices. Her expertise covers multiple therapeutic areas including oncology.

Ramona has served as a consultant in regulatory affairs to the pharmaceutical industry, and has held executive leadership positions in regulatory affairs and quality in the industry with such companies as Sanofi-Aventis and Johnson and Johnson. Following her time as Vice President,



Regulatory Affairs with Bristol- Myers Squibb, she served in the role of Sr. Vice President of Regulatory Affairs and Safety for ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company. Ramona has also served as Vice President of Regulatory Affairs and Quality for public and private biotech companies leading global regulatory strategy, regulatory submissions through product approval and key meetings with global regulatory authorities.

Ramona holds a PhD in Molecular Genetics and Microbiology from Rutgers University – Robert Wood Johnson Medical School, and was a researcher at the Center for Advanced Biotechnology and Medicine. Recognized by the Department of Biomedical Engineering of Rutgers University with the Distinguished Alumni Award, Dr. Lloyd has also served as a member of their Industrial Advisory Board. Ramona earned the professional credential in regulation of healthcare products, Regulatory Affairs Certified (RAC).

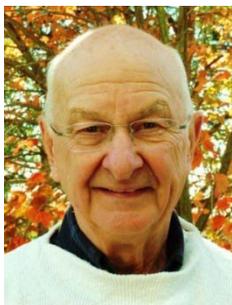


**H. Kim Lyerly, M.D.**

George Barth Geller Professor of Cancer Research and Professor of Surgery, Duke University Medical Center

Kim is the George Barth Geller Professor of Cancer Research and Professor of Surgery at the Duke University Medical Center. He has been named by his peers as one of North Carolina's most outstanding clinical physicians. In addition, he is an internationally recognized expert in cancer therapy and cancer immunotherapy and has published nearly 200 scientific articles and has edited 10 textbooks on surgery, cancer immunotherapy, and novel cancer therapies. He serves on the editorial board of 12 scientific journals. In 2008, Kim was appointed to the National Cancer Advisory Board (NCAB) by President George Bush and was named chair on the Cancer Centers sub-committee of the NCAB. Kim is a highly sought advisor and currently serves on the external advisory boards of the M.D. Anderson Cancer Center, the University of Michigan Cancer Center, the University of Chicago Cancer Center, the University of Alabama Cancer Center, the Boston University Cancer Center, and the Purdue Cancer Center. He also serves as an advisor to the University of Washington, and Case Western Reserve Clinical and Translational Science Institutes. He is currently a member of the Scientific Advisory Board of Susan G. Komen for the Cure. He has previously served as chairperson of the executive committee of the integration panel of the Congressionally Directed Medical Research Programs in Breast Cancer. He also served on American Society of Clinical Oncology's Grants Selection Committee, of which he served as chair in 2006. Kim is a member of the American College of Surgeons, of which he is a fellow. He was invited by former North Carolina Governor Michael Easley to serve on the Advisory Commission of the NC State Museum of Natural Sciences. In 2010, Kim was reappointed as a member of the NC Advisory Committee on Cancer Coordination and Control by Governor Bev Perdue.





**Richard (Mac) V. McCloskey, M.S., M.D.**

Scientific Adviser, Endo Pharmaceuticals

Mac graduated from The University of Rochester Medical School with an M.D. with honors and an M.S. in Microbiology. Post graduate training was at Duke University Medical Center and the National Institutes of Health. He was a founding faculty member of the University of Texas Medical School at San Antonio. He is certified by the American Boards of Internal Medicine and Infectious Diseases, and is an emeritus member of the Infectious Diseases Society of America. Clinical appointments have been as Chair of Medicine at Albert Einstein Medical Center, Daroff Division, and Chief of Infectious Diseases at Presbyterian-University of Pennsylvania Medical Center, both in Philadelphia. Mac was also Vice President of Clinical Research at Centocor and Vice President of Medical Technology at Johnson and Johnson Development Corporation until 2008. He currently is Scientific Adviser for Endo Pharmaceuticals and was a consultant to the Corporate Office of

Science and Technology of Johnson and Johnson from 2008 to 2012. He also is a member of the Sid Martin Biotech Center Advisory Board of the University of Florida.



**Mark Pegram, M.D.**

Professor of Medicine, Stanford University

Mark joined Stanford after five years at the University of Miami Miller School of Medicine, where he was a Sylvester Chair professor of medicine in the Braman Family Breast Cancer Institute, and associate director for clinical research in the University's Sylvester Comprehensive Cancer Center.

Mark earned his undergraduate and medical degrees from the University of North Carolina, and then joined the faculty of UCLA in 1993. He played a major role in the development of the drug Herceptin for the treatment of HER-2 positive breast cancer, which contributes to about twenty percent of all breast cancer cases.

Mark conducted laboratory experiments demonstrating that in combination with standard chemotherapy, Herceptin effectively killed breast cancer cells that overproduced HER-2. Mark and others then conducted clinical trials showing Herceptin improved survival rates and even cured some breast cancer patients. This remains one of the premier examples of bench-to-bedside translational research.

Mark's current research efforts include a continued focus on the cancer-associated gene (or oncogene) that encodes HER-2, and developing new ways to target cancer cells expressing this marker. He is also pursuing various strategies for targeting estrogen receptors, implicated in some 70 percent of all breast cancer cases.





**Robert T. Sarisky, Ph.D.**

Chief Business Officer, FORMA Therapeutics

Rob is an experienced scientific and business professional from the pharmaceutical industry, most recently serving as Vice President of Oncology Business Development and Licensing within Janssen Pharmaceuticals, a Johnson & Johnson company. Prior to that role, he held positions of Vice President of External Research and Early Development within Johnson & Johnson, Sr. Director of Immunology Research at Centocor, and Director of Virology at GlaxoSmithKline Pharmaceuticals.

Rob received his B.S. degree in Biology from the University of Scranton, a Ph.D. in Genetics from the Pennsylvania State University College of Medicine, completed his postdoctoral training at the Johns Hopkins School of Medicine, and holds an M.B.A. in Marketing from Lehigh University. He has authored more than 120 publications and patents and served on the Editorial Board for two scientific journals. He has been active in the academic community by serving on the University of Pennsylvania Executive Advisory Committee for the HHMI Graduate Training in Medical Sciences, the University of Miami Innovation Corporate Advisory Council, the University of North Carolina Innovation Transfer and Development Initiative, adjunct Professor for Drexel University School of Medicine, and an Advisory Board member for Indiana University's Biotechnology Program.



**Bo Saxberg, M.D., Ph.D.**

President, DDO Strategic Services, LLC

Bo Saxberg is originally from Seattle, Washington. He attended the University of Washington, receiving Summa Cum Laude an Honors B.S. degree in Mathematics and an Honors B.S. degree in Chemistry. He then attended Cambridge University in England, earning an Honours B.A./M.A. Cantab. in Physics. Returning to the United States, he received an M.D. degree from Harvard and his Ph.D. in Physics from the Massachusetts Institute of Technology.

Bo was a National Institutes of Health Fellow at MIT from 1989 to 1991, prior to joining Eli Lilly in Indianapolis as a Senior Research Scientist, continuing his prior research interests in QSAR/genomics/proteomics/physiomics. In 1993, he was named Director of Information Sciences at Eli Lilly. This group subsequently led a number of industry pioneering efforts at Lilly, including the first Internet home page for a pharmaceutical company, as well as developing interactive health economic models evolving to disease management, point of care prescribing, and the development of information resources to support modern product portfolio resource allocation decisions.

He joined Johnson & Johnson in 1995 as Vice President, Corporate Staff, Advanced Communications, leading Johnson & Johnson's efforts in Medical Informatics, focusing on new business opportunities related to information technology in healthcare delivery and product development. As part of these efforts, working with both internal and external venture capital resources as well as member companies, the Advanced Communications Group helped to



develop for J&J pioneering creation or investment positions ranging from defined contribution employee benefit models of health insurance, real-time auto-adjudication networks at the point of care supporting cost-quality decisions between doctor and patient, and a variety of technologies in health informatics including telemedicine, clinical studies and outcomes measurement, and electronic medical records. Working with the J&J international pharmaceutical group, innovative programs were created in the development of iterative customer relationships based on clinical information, creating demonstration of product value. Bo and members of the Advanced Communications Group also led the development and implementation of J&J's global policies and procedures for the Internet, including privacy policies, to construct a policy platform to enable future business needs.

In 2002, Bo left J&J to become founder and President of DDO Strategic Services, LLC, ("Design Development Optimization"). He is also founder and Manager of Oro Valley Ventures, LLC, investing in early stage companies. He is continuing his prior work in consulting, venture formation and business development with companies seeking to take leading advantage of change driven by new technologies and information access in health care, with application to product research & development, product and service marketing, financial services innovation, and clinical service innovation. Bo is also a management/advisory board member for a number of entrepreneurial companies, associations and venture firms, including PhDx, IntelliCyt, Boston Millennia Partners, and the Columbia University Center for Advanced Technology.



**David A. Scheinberg, M.D., Ph.D.**

Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program, Sloan- Kettering Institute  
Chair of the Experimental Therapeutics Center and of the Nanotechnology Center, Memorial Sloan-Kettering Cancer Center  
Professor of Medicine and Pharmacology, Weill-Cornell University Medical College

David is currently Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program, Sloan-Kettering Institute. He also founded and Chairs the Experimental Therapeutics Center, and the Nanotechnology Center at Memorial Sloan-Kettering Cancer Center. He is additionally Professor of Medicine and Pharmacology and Co-chair of the Pharmacology graduate program at the Weill-Cornell University Medical College and Professor in the Gerstner-Sloan Kettering Graduate School at MSKCC. From 1992 until 2003, he was Chief of the Leukemia Service at Memorial Hospital. He has been elected into the American Society of Clinical Investigation (ASCI), the Association of American Physicians (AAP), and the Interurban Club. His other awards include the Doris Duke Distinguished Clinical Science Professorship, the Lucille P. Markey Scholarship, Leukemia and Lymphoma Society Translational Investigator Awards, and CapCure Awards. He is an advisor to charitable foundations and cancer centers and sits on the boards of directors of two biotech companies.

David is a physician-scientist, specializing in the care of patients with leukemia and also investigating new therapeutic approaches to cancer, both in the hospital and in the laboratory. The focus of his research is on the discovery and development of novel, specific immuno-therapeutic agents. This includes monoclonal antibodies that target the cell surface of cancers, targeted radiopharmaceuticals that deliver radioactive particles including alpha particles or alpha



particle nanogenerators, and targeted nano-devices for selective cell kill, and therapeutic vaccines targeting the oncogene products that cause the cancers. Eight different therapeutic agents developed by David in his laboratory have reached human clinical trials, which include the first humanized antibodies to treat acute leukemia, the first targeted alpha particle therapies and alpha generators, and the first tumor specific fusion oncogene product vaccines. His laboratory is also investigating cellular resistance mechanisms to these agents. David has published more than 250 papers, chapters, or books in these fields.

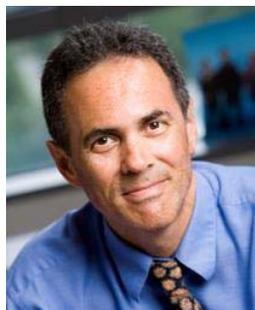


**Ginette Serrero, Ph.D.**

CEO, A&G Pharmaceutical Inc.

Adjunct Professor, University of Maryland School of Pharmacy & University of Maryland School of Medicine

Ginette is CEO of A&G Pharmaceutical, a company developing novel targets in Oncology which she co-founded in 2000 based on her discovery of the GP88/PGRN growth factor protein and her pioneering research demonstrating its importance in the tumorigenesis of many cancers. Under her leadership, A&G has advanced several new therapeutic and diagnostic product candidates into preclinical and clinical development, including two breast cancer diagnostics. In particular, a tissue test that measures GP88 in tumor biopsies as predictor of risk of recurrence in early stage breast cancer patients will be commercialized in Q3 2014. With more than 25 years of in protein biochemistry and cell culture, Ginette is a recognized leader in the field of cancer biology research and development, with particular expertise in the characterization of novel targets involved in cell differentiation and tumorigenesis with a focus on cell adipocyte differentiation, and breast cancer. She is an Adjunct Professor at the University of Maryland School of Pharmacy and at the University of Maryland School of Medicine and a member of the Marlene and Stewart Greenebaum Cancer Center in Baltimore. Prior to founding A&G, Ginette was a Professor at the University of Maryland School of Pharmacy and in the Program in Oncology at the University of Maryland Cancer Center. Before moving to Baltimore, she was Senior Scientist at the W. Alton Jones Cell Science Center in Lake Placid. She has published more than 80 papers, invited chapters, and reviews and is the inventor on 40 issued patents and more than 100 pending applications related to obesity and cancer molecular targets. Ginette is Associate Editor of *In Vitro Cell and Developmental Biology*. She is the 2006 recipient of the Greater Baltimore Life Sciences Entrepreneurial Spirit Award and is a Scientific Advisory board member of the Maryland Industrial Partnerships Program and a Board Member of the Emerging Technology Center located in Baltimore, MD. Ginette received a PhD in Biochemistry from the University of Marseille and a DSc in Cell Biology from the University of Nice.



**Neil L. Spector, M.D.**

Co-Director: Developmental Therapeutics Program, Duke Cancer Institute

Dr. Neil Spector is currently Sandra P. Coates Associate Professor, Departments of Medicine and Pharmacology/Cancer Biology, Duke University School of Medicine; Associate Director, Clinical Research, Breast Cancer Program, Duke Cancer Institute; Co-Director, Developmental Therapeutics Program, Duke Cancer Institute



Dr. Spector received his B.S. from the University of North Carolina at Chapel Hill in 1978. After graduation, Dr. Spector completed his M.D. from the New Jersey Medical School in 1982, and his internal medicine residency at Parkland Hospital, University of Texas-Southwestern Medical School, Dallas, Texas. Dr. Spector then completed a hematology/medical oncology fellowship at the Massachusetts General Hospital/Dana

Farber Cancer Center, Harvard Medical School. Dr. Spector served as an attending physician in hematology and oncology at the Dana-Farber Cancer Institute at Harvard Medical School and then joined the faculty at the University of Miami, Sylvester Comprehensive Cancer Center where he established the bone marrow transplant program. He then returned to North Carolina after accepting a position at GlaxoSmithKline (GSK) where he spent eight years involved in the development of targeted cancer therapies in his official capacity as Director of Exploratory Medical Sciences. During that time, he was an Adjunct Associate Professor of Medicine in the Division of Hematology/Medical Oncology at the UNC Lineberger Comprehensive Cancer Center at the University of North Carolina-Chapel Hill where he remained clinically active.

While at GSK, Dr. Spector successfully oversaw the development of two drugs that have been effective against cancer. First, Dr. Spector directed the Nelarabine development program, which received FDA approval in December 2005 for the treatment of children with acute lymphoblastic leukemia. Second, he directed the translational research program that supported the development of lapatinib (Tykerb), a targeted therapy approved by the FDA in 2007 for the treatment of HER2+ breast cancers.

Dr. Spector joined the faculty at Duke University in September 2006. In his role as the co-Director of the Developmental Therapeutics Program within the Duke Cancer Institute, Dr. Spector directs Duke's effort to make basic-science applicable in the care of cancer patients. His work is aimed at bridging the gap between laboratory scientists in Duke's basic science departments with physicians in the clinics in order to accelerate the transition of new therapies from the laboratory to the patient.



**Colin Turnbull, Ph.D.**

President, Colin Turnbull Consulting, LLC

From 1998 until 2003 I was Chairman of the Oncology Development Team at Schering- Plough Research Institute in NJ as well as Head, Clinical Oncology for most of this time. Since 2003 I have consulted for pharmaceutical clients, carrying out clinical and scientific due diligence on cancer drugs in early development in which there is interest in acquiring development and commercialization rights.





**Subramanian Vaitheeswaran (Vaithee), Ph.D.**

Lecturer, Department of Chemical Engineering at UMass Amherst

Subramanian Vaitheeswaran (Vaithee) was born in Mumbai, India and got his B.S. and M.S. in Physics from the University of Mumbai. In 2004 he earned a Ph.D. in Physics from the University of Maine, using computer simulations to investigate the peculiarities of water in nanoscale confinement. During this time he was a Pre-doctoral Visiting Fellow at the National Institutes of Health in Bethesda, Maryland.

As a Post-doctoral Researcher at the University of Maryland and Rensselaer Polytechnic Institute, he employed computational methods to study proteins and biomaterials. Later, as a Senior Research Fellow at the University of Massachusetts he investigated the fundamental chemistry of biofuel production. He is currently a lecturer in the Department of Chemical Engineering at UMass Amherst.

He is a keen runner and is plotting his second marathon.



**Michael (Mike) J. Vasconcelles, M.D.**

Senior Vice President, Head of Clinical Development, Millennium:  
The Takeda Oncology Company

Mike joined Millennium: The Takeda Oncology Company in 2012 as Senior Vice President, Head of Clinical Development. As part of Millennium's Medical Division Management and Administration, Mike has assumed responsibility for the clinical development strategy and execution of the oncology portfolio.

Prior to 2012, Mike served as Global Therapeutic Area Head, Transplant and Oncology, at Genzyme. He was responsible for the clinical development and product support of Genzyme's hematologic transplant and oncology portfolio. As a member of the Transplant and Oncology Management team, and Chair of the Transplant and Oncology R&D Council, Mike also provided strategic support and oversight to oncology research, business development and commercial strategy for the business. In 2011, following the acquisition of Genzyme by Sanofi, he led the realignment of Genzyme Oncology R&D with Sanofi Global Oncology and was named the Head, Personalized Medicine and Companion Diagnostics.

Before he joined Genzyme, Mike was a full time associate physician at Brigham and Women's Hospital and Dana- Farber Cancer Institute. He remains an associate physician at both institutions. He has been on the faculty of the Harvard Medical School since 1996, where he is currently a clinical instructor of medicine.

Mike received both his B.A. and his M.D. from Northwestern University.





**Elizabeth (Liz) Yamashita, B.S.**

Vice President, Regulatory and Clinical Affairs, Oncobiologics

Liz brings over 30 years of pharmaceutical industry experience with 20+ years in the Regulatory arena. Liz has wide exposure to areas of the pharmaceutical business in small molecule and biotechnology CMC development, clinical and nonclinical development, as well as marketing, and business development.

Liz is currently Vice President, Regulatory and Clinical Affairs at Oncobiologics. Prior to this position, she was Group Vice President, Regulatory Affairs at Savient Pharmaceuticals, Inc. managing all aspects of the regulatory function, and recently lead the Savient team to its first European marketing approval for Krystexxa®(pegloticase) a PEGylated enzyme for the treatment of severe gout. She was a Principal Fellow at ImClone providing regulatory expertise across the ImClone and Lilly biotech pipelines. As Vice President at ImClone Systems, she was responsible for Regulatory CMC strategy and Operations for development and commercial monoclonal antibody projects. Liz began her career at Bristol-Myers Squibb Company holding several positions. Her regulatory focus was working in the CMC arena in the oncology and immunology small and large molecules portfolios. Liz earned her Regulatory Affairs Certification from RAPS in 2002, and holds a B.S. degree in Chemistry from the University of Rochester.



**Nancy E. Zeleniak, B.S.**

President, Optimus Strategies

Zeleniak has more than 27 years of experience in roles that cross scientific research, healthcare market research, business development, marketing, venture relations, and corporate communications. She is best known for conceptualizing and implementing revenue-generating business models and marketing strategies. Working with global leaders, regional organizations and startups, she has worked on the launch and/or marketing teams for 18 biopharmaceuticals and devices. She also helped launch and market more than 80 healthcare services and information products, some of which she conceptualized.

Prior to founding Optimus Strategies, she served as global head of venture relations at PPD, a then public \$1.6B contract research organization. She's held management roles with Burroughs Wellcome, Glaxo, and two startups, and served as associate dean at Duke University. Other roles include the Council of STEM Advisers to the Prime Minister of Belize, and National Space Biomedical Research Institute Industry Council. She has a BS in anthropology with a biology focus from The College of William & Mary.





**Valerie Guild**  
*Advocate Reviewer*

Valerie Guild started AIM at Melanoma after the death of her daughter Charlie from melanoma at the age of 26.

In the area of patient advocacy, among its accomplishments, AIM has led the fight in the US to ban minors from indoor tanning. The AIM website ([www.AIMatMelanoma.org](http://www.AIMatMelanoma.org)) is considered the most comprehensive information site for patients and caregivers, and has launched in France, Italy, Spain, Germany, U.K. and Australia.

In the area of research she has founded, in conjunction with Dr. John Kirkwood, the International Melanoma Working Group (IMWG) an international think tank that brings together world-renowned translational researchers and industry in an effort to move research forward. The Foundation is currently involved in launching a melanoma brain metastases bank and a first of its kind fully annotated primary melanoma tissue bank at four sites throughout the US and a fifth site in Europe.

She serves as the patient representative on the FDA, NCCN, SWOG, and ECOG, as well as the patient advisor to the Skin Cancer Spore and the CDMRP. Valerie holds a BA, MA, and MBA.



**Nora Carbine**  
*Advocate Reviewer*

Nora worked in publishing for more than thirty years on both electronic and print publications. She worked through the transaction from galleys, pasteup, and burning negatives to plates for printing to electronic files, conversion to pdf and html, and digital printing. As a Senior Production Coordinator, she managed production for scientific research journals for a non-profit scientific association in Washington, D.C. (American Geophysical Union). She coordinated file formatting with overseas vendors, as well as directed text and art file in-house revisions from authors' files for web posting. She also sent out special projects for bid, evaluated, awarded, scheduled and supervised projects with in-house graphics staff and external vendors.

Nora was a Client Services Manager for a commercial publishing small business (Mercury Publishing) in Maryland. She handled projects from clients, scheduling in-house desktop publishing, worked with art directors, page makeup, proofreading, layout, ad managers and sales staff, printers, and mail houses.

Nora attended Project LEAD (National Breast Cancer Coalition science training for breast cancer advocates) in 1995, completed Clinical Trials LEAD training in 2003, and served as an advocate reviewer for the California Breast Cancer Research Program (2000, 01 & 02), an NCI advocate reviewer in 2011, and a Department of Defense Breast Cancer Research Program reviewer in 2014. As an advocate representative for the Georgetown Lombardi Cancer Center breast SPORE from 2002 to 2006, Georgetown TBCRC (Translational Breast Cancer Research Consortium) from 2008 to present, and the Georgetown breast cancer advocates' group (GLBCPAC), she has



worked with bench scientists and clinicians evaluating research and clinical trial proposals. She is co-author of a Cochrane Collaboration Systematic Review on the efficacy of prophylactic mastectomy published in 2004 and is currently rewriting its second major revision. She has also edited both the informational web site and a training program for CISN (Cancer Information & Support Network).

She earned a BA in English and Anthropology from the University of Wisconsin, Madison, Wisconsin



**Chris A. Rallis**

Executive-in-Residence, Pappas Ventures

Chris has over 30 years' experience in the life science industry. His experience has been in the areas of legal, business development, strategic planning and general management.

He has been an Executive-in-Residence at Pappas Ventures, a life science venture capital firm based in Durham, NC, since 2008. From April 2006 until June 2007, he was President and Chief Executive Officer of ImmunoBiosciences, Inc., a vaccine technology company then located in Raleigh, NC. Previously, he was President and Chief Operating Officer of Triangle Pharmaceuticals, Inc. ("Triangle"), which was acquired by Gilead Sciences in January 2003 for approximately \$465 million. While at Triangle, he participated in 11 equity financings generating gross proceeds of approximately \$500 million. He was also primarily responsible for all business development activities which included a worldwide alliance with Abbott Laboratories and the in-licensing of 10 compounds. Prior to Triangle, he served in various business development, strategic planning and legal management roles with Burroughs Wellcome, Co. for 13 years. He began his career in 1978 as an attorney with Womble, Carlyle, Sandridge & Rice in Winston-Salem, NC.

Chris currently serves on the boards of Oxygen Biotherapeutics, Inc., Aeolus Pharmaceuticals Inc. and Adherex Technologies Inc. He is on the Audit Committees of all three corporations and chairs the Audit Committees of Aeolus and Adherex..

He received his A.B. degree in economics from Harvard College and his J.D. from Duke University.



**Robert A. Figlin, M.D., F.A.C.P.**

Steven Spielberg Family Chair in Hematology Oncology Professor of Medicine and Biomedical Sciences Director, Division of Hematology Oncology  
Deputy Director, Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center

Robert A. Figlin, MD, FACP, is the Steven Spielberg Family Chair in Hematology Oncology, Professor of Medicine and Biomedical Sciences, Director of the Division of Hematology/Oncology, and Deputy Director of the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center in Los



Angeles, California. Dr. Figlin received his medical degree from the Medical College of Pennsylvania. He completed his residency and chief residency in internal medicine at Cedars-Sinai Medical Center and a fellowship in hematology/oncology at the David Geffen School of Medicine at UCLA. He is an Emeritus Professor of Medicine and Urology at the David Geffen School of Medicine at UCLA.

Prior to joining Cedars-Sinai, Dr. Figlin was the Arthur and Rosalie Kaplan Endowed Chair of the Department of Medical Oncology and Therapeutics Research, and the Associate Director for Clinical Research at the City of Hope Comprehensive Cancer Center. Prior to that, Dr. Figlin served as the Henry Alvin and Carrie L. Meinhardt Endowed Chair in Urologic Oncology and Professor of Medicine and Urology in the Divisions of Hematology/Oncology and Urologic Oncology at the David Geffen School of Medicine at UCLA. Dr Figlin joined the UCLA faculty as Assistant Professor of Medicine in the Division of Hematology/Oncology and was appointed Co-Director of the Jonsson Comprehensive Cancer Center's Oncology Program. He also held the post of Medical Director of the Thoracic and Genitourinary Oncology Program in the Departments of Medicine, Surgery and Urology, and served as Program Director of Solid Tumor Developmental Therapeutics within the Cancer Center. Dr. Figlin serves as Editor for *Kidney Cancer Journal*, and his studies have appeared in *Clinical Cancer Research*, *Journal of Clinical Oncology*, *New England Journal of Medicine*, *Lancet*, *JNCI*, *Lancet Oncology*, and *Journal of Urology*, among others. He has authored over 300 peer reviewed articles, more than 60 book chapters, and has published as editor multiple books in kidney cancer. He is the Editor of the recently released book by Springer Science entitled, *Renal Cell Carcinoma: Translational Biology, Personalized Medicine, and Novel Therapeutic Targets*.

A nationally recognized leader in genitourinary and thoracic oncology, Dr. Figlin's research focuses on renal cell carcinoma and thoracic malignancies. He established and directs the Kidney Cancer Program at Cedars-Sinai Medical Center, which aims to understand the biology of kidney cancer and translate that knowledge into novel treatment approaches. His leadership in developing novel anticancer drugs that avoid the toxicity associated with standard treatments furthers Cedars-Sinai's tradition of compassionate patient care.



**David Edward Weng, M.D., Ph.D.**

Dr. David E. Weng is a board certified medical oncologist with Anne Arundel Medical Center, joining the medical staff in March, 2014. In addition to clinical responsibilities for the care of patients with hematologic and solid tumor malignancies, he is also involved with clinical trials, health care outcomes and quality management research. Dr. Weng has been involved as an investigator in over 30 oncology studies during his research career.

Dr. Weng has over 60 peer-reviewed publications and abstracts in the fields of developmental biology, cancer biology, immunology, and clinical research. He has been an advisor and investigator for multiple biotechnology companies for development of new approaches including target selection, preclinical drug development, chemotherapy cytotoxic agents, hormonal therapies, small molecule agents, monoclonal antibodies, cellular therapies, diagnostics, and imaging.



He was previously the chief medical officer and senior vice president for TetraLogic Pharmaceuticals in Malvern, PA. At TetraLogic, Dr. Weng advanced the clinical development of birinapant, (novel small molecule in the class of Smac mimetic agents) from preclinical studies to phase 2 clinical studies for both solid and hematologic malignancies. In addition, he was primarily responsible for the development of external preclinical and clinical collaborations, and the building of company capabilities in clinical development, operations, regulatory affairs, and data management. At TetraLogic, he oversaw pharmacovigilance, and management of interactions with contract research organizations, key academic institutions and opinion leaders, in the US, Asia, and Europe. Dr. Weng contributed to strategic planning, corporate development, business development, translational studies, preclinical research, and communication with investors.

Before joining the biotechnology industry, Dr. Weng was a faculty member of the Department of Hematology and Medical Oncology and the Taussig Cancer Center at the Cleveland Clinic Foundation from 1998-2006. While at the Clinic, he was a clinical oncologist, seeing patients of all diagnoses and disease stages, with particular expertise in breast cancer. In addition, he contributed to institutional capabilities as director for the Hematology/Medical Oncology Fellowship Program, overseeing the recruitment and training of fellows to careers for both academic and community practice. Dr. Weng was also vice chairman of the Cleveland Clinic Institutional Review Board, overseeing review of new and ongoing programs of clinical research.

Dr. Weng earned his bachelor's degree in biochemical sciences from Harvard University and medical and doctorate degrees from the Johns Hopkins University School of Medicine. He completed his internal medicine residency training at the Johns Hopkins Hospital, followed by fellowship training in medical oncology at the National Cancer Institute. He continues to maintain active licenses for Federal DEA prescription privileges for controlled substances and state medical licensure in Maryland, Ohio, and California.



#### **Grant Williams, M.D.**

Grant Williams, M.D. is a board certified oncologist and regulatory consultant with 25 years of experience focused on oncology drug development including roles in FDA, industry, and consulting. For 16 years (1989 to 2005) he worked for the FDA Division of Oncology Drug Products serving as primary medical reviewer for 8 years, medical team leader for 5 years, and Deputy Division Director to Richard Pazdur, M.D., for 3 years. During his tenure at FDA he drafted guidance documents that are now central to the design and interpretation of pivotal studies for cancer drug approval. This included the Cancer Endpoints Guidance which outlines FDA positions on analysis of PFS, a key endpoint in cancer drug approval. After leaving FDA in 2005 he pursued oncology clinical development at Novartis and GSK. He was a member of the PhRMA statistical subgroup on PFS and coauthored papers on this topic. In September 2008 he formed Williams Cancer Drug Consulting LLC, centered in Wayne, PA, and has consulted extensively for large and small companies on regulatory and development issues related cancer drug approval.





**Lee Greenberger, Ph.D.**

Chief Scientific Officer, Leukemia and Lymphoma Society

Lee has over 25 years experience in Oncology Research and Development. Since September 2013, Lee has been Chief Scientific Officer of the Leukemia and Lymphoma Society. His responsibilities focus on planning and executing the strategy for all LLS research programs, including a grant portfolio with 320 active projects, the Therapy Acceleration Program (TAP) with over 15 opportunities, as well as other research initiatives. Dr. Greenberger guides LLS's efforts to translate innovative research into clinical trials that ultimately will pave the way for new therapies to treat blood cancers. The total annual budget for these activities is approximately \$75 M. Immediately prior to LLS, Dr. Greenberger was global head of search and diligence for oncology and immunology at Bristol-Myers Squibb where he examined opportunities for over 200 oncology companies and helped set the business strategy for oncology and immunology. Prior to that, he served for six years as vice president for research at Enzon Pharmaceuticals where he was responsible for pre-clinical pharmacology, toxicology, process development, and analytical chemistry efforts associated with the discovery and development of oncology assets. Prior to Enzon, Lee held positions of increasing responsibility in the research organizations of Johnson & Johnson and Wyeth Pharmaceuticals, where he began his industry career in 1990 at American Cyanamid/Lederle Laboratories, which was later acquired by Wyeth. He was given the President's Award for his work at Wyeth.

Dr. Greenberger holds a bachelor's degree from the University of Rochester and a Ph.D. from Emory University. He has done post-doctoral work at Columbia University and was on faculty at the Albert Einstein College of Medicine. Dr. Greenberger has produced more than 85 publications, mostly focused on oncology, during his research career.



**Meryl Weinreb**

*Advocate Reviewer*

Meryl Weinreb is a retired pharmaceutical marketing executive with extensive experience in oncology – both from an industry and personal perspective. As a 3 time breast cancer survivor, she was uniquely equipped to successfully lead consumer marketing strategy and execution for AstraZeneca's US oncology portfolio. She was responsible for a number of awarding-winning patient education and support programs for breast, prostate and lung cancer therapies. She led innovative adherence programs, and worked with company researchers to create patient-friendly PI's and clinical protocols. As President of Somerset Lake Consulting, Ms. Weinreb has worked with a number of clients to provide strategic help with a variety of business challenges. Clients have included Abbott Labs, Genentech, Onyx, Cardinal Health and GlaxoSmithKline. These projects have covered a variety of tumor types including breast, non-small cell lung, hepacellular carcinoma, and leukemia. Additionally, for the past 7 years, Ms. Weinreb served on the Executive Board of the Philadelphia affiliate of the Susan G. Komen Foundation, a non-profit organization that educates the community about breast cancer, and funds research, screening and support programs. She continues to serve as the affiliate's Education Chair, and leads public policy initiatives for Komen's Advocacy Alliance in Pennsylvania and Delaware. In 2013, she was invited to join Komen's Advocates in Science Program and has served as a consumer reviewer for the Department of Defense's Breast Cancer Research Program.



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## Questions?

## Key Executive Staff

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### **Operations**

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