

## **BIENNIAL REPORT**

January 1, 2011 to December 31, 2012

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#### **Health Research Science Board Membership Roster**

January 1, 2011 - December 31, 2012

#### Santo M. DiFino, MD, Chair 1

Hematology-Oncology Associates of Central New York, PC Syracuse, NY

#### Beverly Canin 1,6

Breast Cancer Options, Inc. Regional member, Hudson Valley Region

#### Douglas Conklin, PhD 1,4

State University of New York at Albany Albany, NY

#### Victoria Derbyshire, PhD 3

New York State Department of Health Commissioner's Designee Albany, NY

#### Anthony Hay, PhD 3

Cornell University Ithaca, NY

#### James B. Hicks, PhD 1,4

Cold Spring Harbor Laboratory Cold Spring Harbor, NY

#### M. Suzanne Hicks 2,7

Capital Region Action Against Breast Cancer! (CRAAB!) Regional member, Northern NY Region

#### Russell Hilf, PhD 1

University of Rochester School of Medicine and Dentistry Rochester, NY

#### Diana E. Lake, MD 1

Memorial Sloan-Kettering Cancer Center New York, NY

#### Eugene Leff 3, 4

NYS Department of Environmental Conservation Commissioner's Designee Albany, NY

#### Dexter A. McKenzie, MD 1,5

Downstate Medical Services PC Brooklyn, NY

#### Gary Morrow, PhD 1

University of Rochester School of Medicine and Dentistry Rochester, NY

#### Margaret O'Neil 3

NYS Department of Environmental Conservation Commissioner's Designee, alternate Albany, NY

#### Arun Puranik, MD<sup>1</sup>

Image Guided Radiation Therapy Latham, NY

#### Robert Riter 1

Cancer Resource Center of the Finger Lakes Ithaca, NY

#### Neeta Shah, MD 1

North Shore-Long Island Jewish Health Systems New Hyde Park, NY

#### Elinor J. Spring-Mills, PhD 1

SUNY Upstate Medical University Syracuse, NY

#### Marc Wilkenfeld, MD 1

Winthrop University Hospital New York, NY

- 1 Voting member
- 2 Non-voting member
- 3 Ex-officio non-voting member
- 4 Appointed during 2011-2012
- 5 Member until 6/30/2012
- **6** Transitioned from non-voting to voting member during 2011-2012
- 7 Transitioned from voting to non -voting member during 2011-2012

# Health Research Science Board Committee Rosters

January 1, 2011 - December 31, 2012

## Committee on Program Needs and Effectiveness

#### **Santo DiFino, MD, Chair** Hematology-Oncology Associates of Central NY, PC

# **Beverly Canin**Breast Cancer Options, Inc.

# M. Suzanne Hicks Capital Region Action Against Breast Cancer! (CRAAB!)

# **Diana E. Lake, MD**Memorial Sloan-Kettering Cancer Center New York, NY

# **Gary Morrow, PhD**University of Rochester

# **Robert Riter**Cancer Resource Center of the Finger Lakes

# **Neeta Shah, MD**North Shore-Long Island Jewish Health Systems

#### **Committee on Funding and Outreach**

#### Elinor Spring-Mills, PhD, Chair SUNY Upstate Medical University

# **Gary Morrow, PhD**School of Medicine and Dentistry University of Rochester

# Committee on Access to Pesticide Registry and Pesticide Application Information

*Syni-An Hwang, PhD, Chair*NYSDOH, Center for Environmental Health

Erin Bell, PhD
SUNY School of Public Health

William Cooke

Citizens Campaign for the Environment

*Mara Ginsberg, Esq.*Hinman Straub, PC and To Life!

John Hassett, PhD
SUNY College of Environmental Science and Forestry

**David McMaster**Bartlett Tree Experts

Erin O'Leary, PhD SUNY at Stony Brook

Alan Rabideau, PhD SUNY at Buffalo

**Edwin Van Wijngaarden, PhD**University of Rochester Medical Center

H. Pat VogesNassau Suffolk Landscape Gardeners Association

*Mark Wilkenfeld, MD*Winthrop University Hospital

Jeffrey Williams New York Farm Bureau

#### **Department of Health Staff**

#### Wadsworth Center Extramural Grants Administration

#### Bonnie Jo Brautigam

Executive Secretary to the Board Director, Extramural Grants Administration

#### Teresa K. Ascienzo

Associate Accountant

#### Lani Rafferty

Health Program Administrator 2

#### Mary Rogers Ryther

Health Program Administrator 1

# Center for Environmental Health Bureau of Environmental and Occupational Epidemiology

Syni-An Hwang, PhD

Research Scientist 6

Carole Ju, MS

Research Scientist 4

Division of Legal Affairs Bureau of House Counsel

Diana Yang, JD

Senior Attorney

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#### HEALTH RESEARCH SCIENCE BOARD BIENNIAL REPORT 2011-2012

#### **Executive Summary**

The Health Research Science Board (Board, HRSB) of the New York State Department of Health (DOH) was created to support innovative breast cancer scientific research and education projects within New York State. The Board also considers requests for confidential pesticide information for use in specific health-related research projects.

Projects are supported by the Breast Cancer Research and Education Fund, which is financed primarily through voluntary contributions from a check-off mechanism on the New York State Income Tax form; New York State began matching contributions to the Fund in 2002.

The Board is grateful to the many New York State residents who have contributed so generously to the Breast Cancer Research and Education Fund and to the Governor and Legislature for State matching of income tax donations.

Among the accomplishments of the Board and program in 2011-2012 were:

#### Taxpayer Gifts

More than \$900,000 in funds was contributed via the income tax check-off mechanism during the period covered by this biennial report. In addition, proceeds from the sale of Drive for the Cure specialty license plates amounted to more than \$66,000. The total, more than \$1,032,000, is matched by State funds. Notably, the Breast Cancer Research and Education Fund receives more individual gifts and receives a higher average donation than any of the other contribution options offered on the tax return.

#### Health Research Science Board

The composition of the board models the importance of cooperation between New York researchers, physicians and the breast cancer advocacy community. Two voting members and two ex-officio non-voting members were appointed during this biennial period. Five voting seat and two non-voting seat vacancies remained at the end of 2012. The Board met twice and conducted one public hearing during 2011-2012.

- Health Science Research Board Committee on Program Needs and Effectiveness
   The Committee on Program Needs and Effectiveness met twice during 2011-2012 and set a
   strategic course for the continued success of the program that was adopted by the Board at
   its June 22, 2012 meeting. This strategy includes:
  - Peter T. Rowley Breast Cancer Research Projects Awards and Request for Applications

Rowley Awards support preliminary testing of novel or exploratory hypotheses related to breast cancer. The Board recommended funding 10 Rowley Awards totaling \$3.6 million. Institutions recommended for funding are located throughout New York State (see page 8). The Rowley Request for Applications (RFA) has been approved by the Board for annual issuance.

#### Patricia S. Brown Breast Cancer Education Community-Based Demonstration Projects Request for Applications

The Patricia S. Brown Breast Cancer Education Community-Based Demonstration Projects Award (Brown) encourages Community Based Organizations to collaborate with researchers from accredited academic institutions to design and assess new breast cancer education programs and materials. The Board voted to issue this RFA every other year, and funded one such project during this reporting period.

#### Healthcare Practitioner Request for Applications

Awards from this RFA will stimulate breast cancer education research projects that will develop communication skills programs targeted to certain healthcare practitioners, with the goal of facilitating partnerships with and fostering breast health literacy among their patients. The Board voted to issue this RFA every other year, alternating with the Brown RFA.

The Board appreciates the opportunity to work for the citizens of New York State to support critical biomedical and educational research in breast cancer, while simultaneously stimulating economic development within New York. The Board looks forward to and anticipates continued progress and success in achieving its mandates.

# STATE OF NEW YORK, DEPARTMENT OF HEALTH HEALTH RESEARCH SCIENCE BOARD January 1, 2011 to December 31, 2012

#### I. INTRODUCTION

Breast cancer is one of the most common cancers among women in New York State.

Each year in New York, nearly 14,000 women are diagnosed with breast cancer and over 2,700 women die from the disease. It is estimated that one in eight women will develop breast cancer sometime during her life.

While men are also diagnosed with breast cancer, the incidence is very rare. About 125 men are diagnosed with breast cancer each year in New York State.

The Health Research Science Board (HRSB, Board) of the New York State Department of Health (DOH) was created to support innovative breast cancer scientific research and education projects within New York State. Additionally, the Board considers requests for confidential pesticide information from the New York State Pesticide Sales and Use Database for specific health-related research projects.

The Board was established pursuant to Chapter 279 of the Laws of 1996 (amended by Chapter 219 of the Laws of 1997 and Chapter 32 of the Laws of 2008). The legislation is codified in Title 1-B, Article 24 (§ 2410-2413) of the New York State Public Health Law (PHL). Chapter 279 also established the Breast Cancer Research and Education Fund (Fund), to be financed through voluntary contributions from a check-off mechanism on the New York State Income Tax form (§ 97-yy of the State Finance Law). Pursuant to Chapter 550 of the Laws of 2000, New York State began matching those donations in 2002.

Additionally, Chapter 279 established a Pesticide Sales and Use Database, maintained by the New York State Department of Environmental Conservation (DEC) in conjunction with Cornell University, pursuant to Environmental Conservation Law (ECL) § 33-1201 through § 33-1207. The database contains mandated reports of pesticide applications by all commercial applicators. In addition, entities that offer restricted-use pesticides for sale to private applicators for use in agricultural crop production must report any such sales.

The Board's primary responsibilities, as delineated in PHL § 2411(1), include:

Recommending awards for research and education

The Board makes recommendations to solicit, receive, and review applications from various entities for funds to conduct research and education programs focusing on the causes, prevention, screening, treatment and cure of breast cancer. Such research funding is distributed through a formal Request for Applications (RFA) process leading into executed contracts.

• Reviewing requests for access to confidential pesticide-related data

The Board is responsible for evaluating requests for and granting access to confidential pesticide-related data collected and maintained in the New York State Pesticide Sales and Use Database. The data include: 1) reports of pesticide applications submitted to DEC by commercial applicators and technicians; 2) reports of sales of restricted pesticides to private applicators; and 3) reports of general-use pesticide sales for use in agricultural crop production. While a large portion of the database is public, some of it is confidential and may only be released to those engaging in human health-related research, pursuant to the Board's approval and contingent on compliance with established criteria.

#### Issuing Biennial Reports

This, the Board's eighth biennial report, summarizes its 2011-2012 activities and program operations with regard to its major functions. As required by statute, this biennial report also includes:

- The Board's recommendations on matters including, but not limited to, the types of
  pesticide data useful for breast, prostate or testicular cancer research; and whether
  private citizen use of residential pesticides should be covered in the reporting
  requirements;
- 2. A summary of research requests for confidential pesticide data granted and denied;
- An evaluation by the Commissioners of Health and Environmental Conservation, as well as the Board, of the basis, efficiency and scientific utility of the information derived from pesticide reporting pursuant to ECL § 33-1205 and 33-1207, and recommendations on whether such an information system should be modified or continued; and
- 4. A summary of comments and recommendations presented by the public at the Board's public hearings.

The Board's enabling statutes are found in Appendices I - V and the bylaws governing the Board's activities are found in Appendix VI.

#### II. BOARD ORGANIZATION and MEMBERSHIP

The Board's original statutory composition was amended in 2008 to enlarge and reconfigure the Board and to include voting representation from breast cancer survivors from various geographic regions of the state. This reorganization reflects a commitment to increasing coordination between the scientific, medical and breast cancer advocacy communities. As a result, the Board now includes 17 voting members and six non-voting members, as follows:

- 12 voting doctoral-level scientists and physicians appointed by the Governor and the Legislature;
- 1 voting breast cancer survivor appointed by the Governor;
- 1 voting prostate or testicular cancer survivor appointed by the Governor;

- 3 voting regional breast cancer survivors who are actively involved with community-based, grass-roots breast cancer organizations: 1 appointed by the Governor, and 1 nominated by the Assembly Speaker and Temporary President of the Senate each and appointed by the Governor;
- 3 non-voting regional breast cancer survivors who are actively involved with community-based, grass-roots breast cancer organizations: 1 appointed by the Governor, and 1 nominated by the Assembly Speaker and Temporary President of the Senate each and appointed by the Governor; and
- 3 non-voting *ex-officio* members representing the DOH, the DEC, and Cornell University's Institute for Comparative and Environmental Toxicology.

The Board's Chair is designated by the Governor. Member terms are three years in length, with reappointment permitted. An individual member's Board service may continue beyond the prescribed term until the member is replaced. This process is designed for stability and continuity of the Board.

As of December 31, 2012, five voting vacancies remained, including two voting scientists/ researchers, two voting regional breast cancer survivors (New York City and Central NY) and one prostate or testicular cancer survivor. Two non-voting regional breast cancer survivor seats (Long Island and Western NY) are also vacant. With this number of vacancies, nearly 30 percent of voting members, it is often uncertain whether quorum requirements can be met so that business can be conducted.

For more information on members, see Appendix VII.

While the legislation does not allocate funding for support staff and administration of the program, the DOH supplies such support to the Board. In addition, DEC staff maintains the Pesticide Sales and Use Database and evaluates the basis, efficiency and scientific utility of the information derived from pesticide reporting.

#### **III. BOARD OPERATIONS**

#### Meetings

PHL § 2411(1)(h) requires the Board to meet at least four times annually, and one of those meetings must be a public hearing. Meetings are announced at least two weeks in advance and are open to the public. Additionally, an audio recording of each meeting is available via the Department of Health's public website at <a href="http://www.health.state.ny.us/events/webcasts/archive/">http://www.health.state.ny.us/events/webcasts/archive/</a> for 30 days after a meeting, opening the proceedings to a wide audience. Agendas and approved minutes are posted on the program's website at: <a href="http://www.wadsworth.org/breastcancer/">http://www.wadsworth.org/breastcancer/</a>, and are available upon request from the Board's Executive Secretary.

Due to lack of a quorum, the Board was not able to meet in 2011, although several attempts to meet were made. In 2012, the Board held a business meeting on June 22 in Syracuse with videoconference sites in New York City, Albany and Rochester. During that meeting, the Board recommended 10 awards in response to the Peter T. Rowley Scientific Research Projects RFA, approved the draft 2009-2010 Biennial Report, approved meeting minutes, approved the issuance of the Patricia S. Brown Community-Based Organization Education Demonstration Project Awards RFA and the Healthcare Practitioner Education Research RFA, heard a

proposal to amend bylaws and voted to allow an extension for the use of confidential pesticide data for a New York researcher. The Board also met on October 19, 2012 to hear research presentations from funded researchers, review and approve the draft 2011-2012 Biennial Report, approve a bylaws change and hold a public hearing.

#### **Bylaws**

At its October 19, 2012 meeting, the Board approved an amendment to the Bylaws to remove the need for a formal vote of the Board to consider a seat vacant if a seated Board member does not attend three consecutive meetings or respond to three or more meeting availability inquiries.

The current Bylaws can be found in their entirety in Appendix VI of this report.

#### **Committees**

The Committee on Program Needs and Effectiveness makes recommendations to the Board on program emphasis and scope, the award process and program evaluation. This Committee met on February 8, 2011 to review the draft Healthcare Practitioner Education Research RFA, and at that meeting recommended that it be presented to the Board for their approval at the next Board meeting. The RFA was presented to and approved by the Board on June 22, 2012. With funding mechanisms established, the Committee's next focus will be program evaluation.

Prompted by the findings stated in the DEC's report, highlighting the inefficiencies of pesticide data collection efforts, the Committee met on November 29, 2012 to discuss and evaluate the effectiveness of pesticide reporting. The Committee plans to provide its recommendations to the full Board during 2013.

The Committee on Funding and Outreach makes recommendations to the Board for final action with regard to developing innovative and effective strategies that will maximize the resources and public awareness of Board initiatives. Recommendations made in 2010 were acted upon by DOH during the reporting period. This Committee lost several members and was not able to meet during this biennial period.

The Committee on Access to Pesticide Registry and Pesticide Application Information reviews requests by researchers for confidential pesticide registry information and confidential pesticide application information for use in human health-related research projects. The Committee did not receive any requests for confidential pesticide data, so did not meet during the reporting period.

#### **Public Hearings**

In accordance with the Board's enabling legislation, a public hearing was held on October 19, 2012. No public hearing was held in 2011, since a meeting with a quorum could not be convened.

In addition to programmatic updates from the Board's Executive Secretary, the DEC Commissioner's designee provides a report on the efficiency and utility of pesticide reporting at each annual public hearing. The 2011-2012 DEC report can be found in Appendix IX of this document. The report served as the basis for a decision by HRSB's Committee on Program Needs and Effectiveness to evaluate the efficiency and utility of the pesticide use reporting program from inception to the present.

Comments made during Public Hearing and remarks offered during periods set aside for public comment during regular Board meetings may be found in Appendix VIII of this report.

#### Presentations and Reports to the Board

#### **Presentations**

During the October 19, 2012 meeting, Margaret Roberts of CRAAB!, the recipient of the 2009 Patricia S. Brown Breast Cancer Education Community Based Demonstration Project Award, gave a presentation to the Board entitled "True Burden of Breast Cancer Education and Demonstration Project." The project is designed to increase knowledge levels concerning the causation and natural history of breast cancer, produce medically and scientifically accurate breast cancer educational programs and materials, increase knowledge of breast cancer, improve behaviors aimed at reducing the risk of developing breast cancer, and develop innovative educational tools regarding breast cancer risk factors that can be used in communities.

During the October 19, 2012 meeting, Yuval Kluger, PhD, of New York University (NYU), presented "A Quantitative Immunofluorescence Based Approach to Classification of Intermediate Recurrence Risk Early Stage Breast Cancer Patients". Dr. Kluger was the recipient of a 2010 Peter T. Rowley Breast Cancer Scientific Research Project Award. He is working with collaborators at Yale University to develop an easier-to-use, more accurate biomarker test for categorizing breast cancer patients based on their risk of developing metastatic disease. Under the existing biomarker test, patients are placed into low, intermediate or high risk for developing metastatic disease. Those in the high and intermediate risk categories receive chemotherapy, although the benefit of receiving chemotherapy to those in the intermediate group is questionable. The new biomarker technology is expected to more accurately categorize those in the intermediate group and is being used to study tumors from three cohorts of patients treated at Yale and NYU. Six hundred samples are being analyzed for 14 protein markers and results are being compared to those available from the commercial oncotype test to evaluate the new test's accuracy.

#### Reports

During 2011-2012, the Board heard the following report:

#### October 19, 2012

Margaret O'Neil, DEC, reported on "Pesticide Use and Reporting" at the annual public hearing to fulfill the statutory mandate to report on the basis, efficiency and scientific utility of the information derived from pesticide reporting. See Appendix IX.

#### IV. PROGRAM FUNDS

The Breast Cancer Research and Education Fund provides support for contracts executed by the DOH on behalf of the Board. The Fund is financed by donations made by individuals and corporations on State income tax forms, direct gifts to the Fund, and one-half of the proceeds from sales of Drive for the Cure specialty license plates (Tax Law § 209-D and 627; and Vehicle and Traffic Law § 404-q). In 2002, New York State began matching income tax donations and license plate proceeds to the Fund. Deposits to the Fund since its inception in 1996 are presented on the following page.

Table 1. Breast Cancer Research Fund Revenues, 1997-2012

SFY	<u>Tax</u> <u>Returns</u>	<u>License</u> <u>Plates</u>	Total Donations	State Match	Interest (SFY)	Actual SFY Deposits	Cumulative Deposits
96/97	\$23,641	\$0	\$23,641	\$0	\$3	\$23,644	\$23,644
97/98	\$693,863	\$0	\$693,863	\$0	\$28,403	\$722,266	\$745,910
98/99	\$509,209	\$0	\$509,209	\$0	\$60,571	\$569,780	\$1,315,690
99/00	\$586,405	\$0	\$586,405	\$0	\$85,499	\$671,904	\$1,987,594
00/01	\$708,462	\$1,900	\$710,362	\$0	\$119,114	\$829,476	\$2,817,070
01/02	\$572,653	\$35,094	\$607,747	\$600,000	\$79,405	\$1,287,152	\$4,104,222
02/03	\$580,949	\$18,263	\$599,212	\$650,000	\$52,056	\$1,301,268	\$5,405,490
03/04	\$475,445	\$55,750	\$531,195	\$600,000	\$36,127	\$1,167,322	\$6,572,812
04/05	\$557,357	\$29,038	\$586,395	\$575,000	\$55,013	\$1,216,408	\$7,789,220
05/06	\$556,406	\$58,213	\$614,619	\$650,000	\$156,285	\$1,420,904	\$9,210,124
06/07	\$386,993	\$28,618	\$415,611	\$650,000	\$294,787	\$1,360,398	\$10,570,522
07/08	\$607,783	\$47,443	\$655,226	\$650,000	\$292,431	\$1,597,657	\$12,168,179
08/09	\$619,293	\$30,988	\$650,281	\$0	\$107,267	\$757,548	\$12,925,727
09/10	\$535,451	\$42,388	\$577,839	\$650,281	\$20,235	\$1,248,355	\$14,174,082
10/11	\$475,340	\$28,950	\$504,290	\$577,839	\$16,861	\$1,098,990	\$15,273,072
11/12	\$491,257	\$37,075	\$528,332	\$504,125	\$12,013	\$1,044,470	\$16,317,542
12/13*	\$258,243	\$16,713	\$274,956	\$0	\$10,561	\$285,517	<u>\$16,603,059</u>
All Years	\$8,638,750	<u>\$430,433</u>	\$9,069,183	<u>\$6,107,245</u>	<u>\$1,426,631</u>	<u>\$16,603,059</u>	

<sup>\*</sup>through December 31, 2012

#### V. MAJOR ACTIVITIES OF THE BOARD AND PROGRAM

The Board monitors advances in the field and solicits input and recommendations for future projects. The Board's major responsibilities are to:

- Award funds for research and education projects; and
- Advise on pesticide-related issues and oversee access to confidential data from the Pesticide Sales and Use Database.

#### Breast Cancer Research and Education Projects

In keeping with its mandate, the Board solicits, receives, and reviews applications for funding from public and private organizations in New York State. The Board expects outcomes of supported activities to benefit subsequent breast cancer research or education efforts, breast cancer public health policy or the continuum of breast cancer care – from prevention to treatment, survivorship and cure. To fulfill this vision, applicants for funding are invited to address topics or issues related to breast cancer biology, causation, prevention, detection or screening, treatment (including treatment of its effects) or cure. Any investigative approach

appropriate to the application topic may be pursued, including, but not limited to, basic, behavioral, clinical, demographic, environmental, epidemiological, psychosocial or translational research.

The Board has recommended that funds for scientific research be used to support preliminary testing of novel or exploratory hypotheses related to breast cancer, and that funds for education projects be used to plan and assess new breast cancer education and training programs and materials. Through the use of these targeted RFAs, the Board has recommended 107 scientific and education research projects for funding, and the DOH has committed more than \$14 million to support these programs via contracts since its first funding competition in 1998. Many of the scientific projects undertaken are innovative, high-risk/high-reward and provide the basis for receipt by investigators of ongoing financial support from larger funding agencies.

Table 2. Summary of HRSB Research Award Activities, 1998-2012

	FUNDS	FUNDS	
YEAR	COMMITTED	DISBURSED	AWARDS
			18 EMPIRE (EMPowerment Through Innovative
			Research and Education) Awards and
1998	\$1,461,892	\$1,087,985	9 Postdoctoral Fellowship Awards
			19 EMPIRE Awards and
2001	\$2,700,000	\$2,669,152	8 Postdoctoral Fellowship Awards
			4 Community-Based Organization
2002	\$299,998	\$188,821	Demonstration Awards
2004	\$3,588,122	\$3,262,828	30 Postdoctoral Fellowship Awards
			1 Patricia S. Brown Breast Cancer Education
2009	\$149,942	\$148,942	Community-Based Demonstration
			7 Peter T. Rowley Breast Cancer Research Project
2010	\$2,441,295	\$1,472,204	Awards (formerly EMPIRE)
2010	\$177,270	\$0	1 Postdoctoral Fellowship (declined)
			10 Peter T. Rowley Breast Cancer Scientific Research
2011	\$3,597,800	\$0	Project Awards
TOTAL	\$14,416,319	\$8,829,932	107 Awards

#### Progress in Funded Research Projects

Previously unreported highlights of accomplishments related to HRSB scientific and educational research projects appear in Appendix X. Publications and meeting abstracts regarding HRSB funded research are reported in Appendix XI.

## 2011 Peter T. Rowley Breast Cancer Research Project and Postdoctoral Fellowship Awards RFA (Cycle 2)

Peter T. Rowley Breast Cancer Research Project Awards RFA provides initial support for preliminary testing of novel or exploratory hypotheses related to breast cancer. Recipients are expected to open a new area of investigation, satisfactorily test a novel hypothesis, or produce viable data for preparation of a full-scale research application to another organization.

Rowley projects constitute self-contained, hypothesis-driven research. Projects are considered innovative, developmental or exploratory in nature, and target new avenues of breast cancer research. Funded projects may include those considered highly speculative or exploratory that

may not be based on pilot data, but have the potential for high scientific payoff. Researchers may seek to apply or develop state-of-the-art technologies, tools or resources for breast cancer research.

Fifty (50) Rowley applications were received in response to the 2011 RFA; the Board recommended ten applications for funding, and recommended three others if funding becomes available. Proposals cover a range of breast cancer research projects, including studies to understand mutations in normal mammary gland development and breast cancer; developing a new paradigm to discover novel breast cancer drug targets, investigating and targeting interactions between cancer and the microenvironment in breast to brain metastasis, immune response against breast cancer and how it is affected by metabolic energy, and suppression of basal-like breast cancer.

Table 3. Summary of 2011 Rowley Award Recommendations

Principal		Amount	
Investigator	Institution	Awarded	Project Title
	Albert Einstein		Consequences of GATA3 Mutation for Normal Mammary
Paraic Kenny	College of Medicine	\$360,000	Gland Development and Breast Cancer
			Developing a New Paradigm to Discover Novel Breast
Rodney Rothstein	Columbia University	\$360,000	Cancer Drug Targets
	Sloan-Kettering Institute		Investigating and Targeting Interactions Between Cancer
Johanna Joyce	for Cancer Research	\$360,000	and the Microenvironment in Breast to Brain Metastasis
	Albert Einstein		Understanding the Role of Normal Mammary Stem Cell
Wenjun Guo	College of Medicine	\$360,000	Program in Breast Cancer
	Roswell Park		Is the Immune Response Against Breast Cancer Inhibited
Elizabeth Repasky	Cancer Institute	\$357,800	by Lack of Available Metabolic Energy?
	New York University		
Pamela Cowin	School of Medicine	\$360,000	The Role of Gpr 125 in Breast Development and Cancer
Richard Baer	Columbia University	\$360,000	BARD1 Suppression of Basal-Like Breast Cancer
	Albert Einstein		Stromal Contribution of the S100A4 Metastasis Factor to
Anne Bresnick	College of Medicine	\$360,000	Tumor Invasion
	Albert Einstein		
Jeffrey Pollard	College of Medicine	\$360,000	Macrophages and Immunosuppression in Breast Cancer
	Weill Cornell		
Xiaojing Ma	Medical College	\$360,000	Targeting CCL5 in Triple Negative Breast Cancer

Overview of Rowley Research Applications Recommended for Funding

**Paraic Kenny**, **PhD**, Albert Einstein College of Medicine, "Consequences of GAGA3 Mutation for Normal Mammary Gland Development and Breast Cancer," 1/1/13 – 12/31/14, \$360,000.

The protein GATA3 is a transcription factor that functions like a molecular switch in breast development, controlling the expression of a large number of genes. Studies have indicated that GATA3 may play a role in the development of breast cancer and recent studies have identified mutations in GATA3 in breast cancer. The Principal Investigator (PI) will investigate the role of mutant protein GATA3 at all stages of mammary gland development through postlactation/involution and in tumorigenesis or tumor promotion. GATA3 is coordinately expressed along with the estrogen receptor–alpha in breast cancer cells and cell lines. The PI will investigate whether this form of GATA3 promotes tumor formation and/or growth. The PI will also analyze the effect of mutant GATA3 knockdown in the human breast cancer cell line MCF7 using siRNA.

This study will be the first to define the function of the mutant GATA3 protein, and to understand how changes in this gene affect breast development and cancer formation. Since GATA3 is mutated in the most common type of human breast cancer, estrogen receptor positive, understanding how this gene functions may lead to new diagnostic assays and potentially new therapeutic approaches once processes controlled by the mutant protein are understood.

**Rodney Rothstein, PhD,** Columbia University, "Developing a New Paradigm to Discover Novel Breast Cancer Drug Targets," 1/1/13 – 12/31/14, \$360,000.

Triple-negative breast cancers are defined by lack of expression of estrogen, progesterone, and HER2 receptors. There are currently no drug treatments specific for this most aggressive form of breast cancer, so identification of new ways to attack these tumors is an urgent unmet need. The investigator and collaborator have pioneered a completely novel way of identifying new drug targets using a technology to translate what is known about protein expression patterns in these tumors into a simple model system using yeast. They have identified processes critical for survival that depend on these expression patterns, which are then translated back to triple negative breast cancer to find new drugs and drug targets that specifically and effectively kill these tumors.

Preliminary experiments have shown that the drug cyclosporine can specifically kill tumor cells that lack the PTEN protein, a common trait of triple negative breast cancer cells. Based on this proof of principle, they will continue this work using protein expression data from well known genetic lesions in triple negative breast cancer, which include loss of function of the proteins PTEN, p53, and Rb. They will validate initial observations of cyclosporine action in PTEN-deficient cancer using a mouse model, and also identify the mechanism of how cyclosporine works to kill the cells. The investigators anticipate finding several new drug targets or drugs over the next two years that can specifically kill triple negative breast cancer cells. Identification of additional targets to fight this disease will have clinical impact and will also significantly improve our understanding of the biology of the disease. This approach is applicable to any type of cancer and can be used to find ways of treating any disease state that has been defined by a specific pattern of cell protein expression.

**Johanna Joyce, PhD**, Sloan-Kettering Institute for Cancer Research, "Investigating and Targeting Interactions Between Cancer and the Microenvironment in Breast to Brain Metastasis," 1/1/13 – 12/31/14, \$360,000.

The PI plans to develop strategies to investigate and target tumor-stroma interactions in breast cancer metastasis to the brain. The hypothesis is that stromal cells in the brain microenvironment promote metastasis of breast cancer cells. This hypothesis is based on preliminary data showing that the enzyme cathepsin S produced by both the tumor and the brain stroma is important in the development of cancer metastases to the brain. The PI will determine the mechanism by which cathepsin S promotes metastases to the brain, investigate cathepsin S as a therapeutic target in brain metastases and seek to target the cancer-promoting functions of tumor-associated macrophages in brain metastases.

**Wenjun Guo, PhD**, Albert Einstein College of Medicine, "Understanding the Role of Normal Mammary Stem Cell Program in Breast Cancer," 1/1/13 – 12/31/14, \$360,000.

In many cancers, only a small population of the cancer cells within a tumor mass is truly capable of forming tumors, while the majority of cancer cells have lost such ability. Tumor-forming and

non-tumor-forming cells are organized in a hierarchical relationship, in which the tumor-forming cells generate both tumor-forming and non-tumor-forming cells. Such a hierarchy resembles those of stem cells and differentiated cells within normal tissues. Therefore, tumor-forming cells are often referred to as cancer stem cells to reflect that these cells are the driving force of tumor growth and progression. However, the precise identity of cancer stem cells and how they are regulated remain poorly understood.

Because of the similarity of cancer stem cells and normal stem cells, it has been speculated that these two types of cells share common genes that maintain the stem-cell identity and allow stem cells to reproduce (i.e. self-renew). The investigative team has found two genes that are necessary for the formation and maintenance of normal breast stem cells. They will investigate whether these two stem-cell genes play a role in generating and maintaining breast cancer stem cells. In addition, using these two genes, they will develop a method to identify breast cancer stem cells within tumors.

Indentifying cancer stem cells and understanding how cancer stem cells survive and self-renew are important for developing effective cancer therapies; the key regulators can be potential drug targets for eliminating cancer stem cells.

**Elizabeth Repasky, PhD**, Roswell Park Cancer Institute, "Is the Immune Response Against Breast Cancer Inhibited by Lack of Available Metabolic Energy?" 1/1/13 – 12/31/14, \$360,000.

This proposal is based on the novel premise that many patients with breast cancer are so drained of metabolic energy that their immune systems cannot become fully activated. It is known that mounting an immune response against tumors requires a great deal of energy. While studying mice bearing breast tumors, the investigators were surprised to discover that they could divert energy toward the bioenergetically demanding process of mounting a more effective immune response against tumors simply by reducing the amount of energy used for maintaining body temperature (a major energy consuming metabolic process). The study is designed to investigate the complex mechanisms underlying this striking new observation and to identify specific immune cells and signaling mechanisms that can be specifically addressed therapeutically.

This work will be conducted using a clinically relevant murine model of breast cancer (4T1), and will include assessment of tumor growth in mice given a high fat diet which may simulate some clinical situations. Moreover, the research team will determine whether the response of tumors to therapy by metabolic energy conservation can be improved.

Although there is considerable attention being devoted to the role of diet and exercise on breast cancer, these are only some of the ways that allocation of metabolic energy could impact cancer or the patient's ability to respond to therapy. Therefore, exploring other underlying mechanisms by which metabolism or energy allocation can affect the patient's ability to mount a more effective immune response against her own tumor is highly significant. Working with clinical and epidemiological collaborators, the researchers expect to be able to quickly translate the results of this study into clinical development of new, energy conserving strategies that can supplement current breast cancer therapies. If proven, the results of this research could improve overall survival for thousands of women each year.

**Pamela Cowin, PhD**, NYU School of Medicine, "The Role of Gpr125 in Breast Development and Cancer," 1/1/13 – 12/31/14, \$360,000.

The objective of this proposal is to develop a mouse line to test the potency and transformation sensitivity of the protein G-protein coupled receptor 125 (Gpr125) subpopulations during specific developmental windows of breast cancer susceptibility.

During embryonic development, a subpopulation of skin cells becomes designated as mammary stem cells which migrate together to form the mammary tree. During puberty, a subset of these cells found at each branch tip generates a lineage of daughters that form the permanent mammary tree. Some daughter cells scattered along the branches assume the role of adult breast stem cells and cyclically generate side-branches and alveoli during each pregnancy.

The researchers have identified a gene that demarcates each of these mammary stem cell populations and plan to genetically engineer a mouse to express a fluorescent reporter of this gene activity. This will allow identification of mammary stem cells, labeling of their cell progeny with a second fluorescent marker and permit the earliest stages of the mammary lineage to be studied. Further, the researchers will target an oncogene to mammary stem cell populations at different times during development to determine if they are potential sources of breast cancer.

The novel biomarker has the potential to allow visualization of mammary stem or early progenitor cells and thus may have prognostic value and provide a tool to track and eradicate cellular sources of tumor recurrence. These studies will increase the understanding of the links between changes in breast stem cells during development and later breast cancer risk.

**Richard Baer, PhD,** Columbia University, "BARD1 Suppression of Basal-Like Breast Cancer," 1/1/13 – 12/31/14, \$360,000.

BRCA1 is a gene that produces a protein that helps repair damaged deoxyribonucleic acid, or DNA. Germline mutations of the gene BRCA1 are a major cause of familial breast cancer. Women with this mutation have an increased risk of "basal-like" or "triple-negative" subtype of breast cancer, an aggressive malignancy with an especially poor prognosis.

The investigators previously showed that BRCA1 interacts with a related protein BARD1 to form the BRCA1/BARD1 heterodimer and that its tumor suppression activity is mediated by the heterodimer. Recently, tumor-causing mutations of the BARD1 gene were identified in patients with familial breast cancer, suggesting that BARD1 is itself a clinically relevant tumor suppressor.

Since the discovery of BRCA1, there has been considerable progress in determining its various biochemical and cellular functions, but none of these functions had been tested for their relevance to tumor suppression. To bridge this gap, the researchers developed an experimental model of the basal-like breast carcinomas that arise in women who carry BRCA1 mutations. For this project, the model will be used to define the molecular mechanisms in which BARD1 promotes tumor suppression by the BRCA1/BARD1 heterodimer.

By defining basic mechanisms by which BRCA1 and its partner protein BARD1 suppress tumor formation, this study should uncover novel molecular targets and strategies for therapeutic intervention. Although patient-related benefits may be long-term, the fundamental discoveries that emerge may ultimately have a greater impact on the prevention and treatment of breast cancer.

**Anne Bresnick, PhD**, Albert Einstein College of Medicine, "Stromal Contribution of the S100A4 Metastasis Factor to Tumor Invasion," 1/1/13 – 12/31/14, \$360,000.

The leading cause of mortality in breast cancer patients is metastasis, which is the ability of malignant cells to leave the primary tumor, travel to distant sites within the body and form secondary tumors. It is now recognized that interactions between tumor cells and the normal cells of the patient that surround these tumor cells are crucial for driving tumor progression and metastasis. The unique protein S100A4 has been demonstrated to have a direct role in tumor metastasis. Studies in animal models of breast cancer have demonstrated that S100A4 overexpression in breast tumor cells causes tumor metastasis. Recently, though, studies have shown that S100A4 expression in cells surrounding the tumor has an equally important role in promoting tumor progression.

Studies in the investigator's laboratory indicate that S100A4 is released by macrophages, and functions as a signaling factor to promote tumor invasion. Based on these findings, the investigator will examine how released or extracellular S100A4 promotes breast tumor invasion, develop reagents that block the activity of extracellular S100A4 and use these reagents to test the role of extracellular S100A4 in promoting tumor metastasis in animal models of breast cancer.

Currently, no therapeutic approaches target metastasis. Thus, these studies are unique since they address the biological underpinnings of breast tumor metastasis and will have potential therapeutic implications. Furthermore this work represents a paradigm shift, since extracellular S100A4 and not intracellular S100A4 is the therapeutic target. If successful, this work will represent a novel treatment strategy for breast cancer that directly focuses on metastasis itself.

**Jeffrey Pollard, PhD**, Albert Einstein College of Medicine, "Macrophages and Immunosuppression in Breast Cancer," 1/1/13 – 12/31/14, \$360,000.

Breast cancer metastasis is almost entirely incurable. Unfortunately, there has been no change in overall survival of women with breast cancer metastases over the last twenty years, indicating resistance to current therapies. Current therapeutic strategies are inadequate and novel approaches for treatment are needed.

In mouse models of breast cancer, the investigators have shown that removal of macrophages, normal cells belonging to the immune system, blocks tumor progression and metastasis. Macrophages have several pro-tumoral functions, including the ability to restrict immune reactions against malignant cells. This activity is poorly understood and this proposal aims to identify the mechanism whereby macrophages inhibit anti-tumor immune responses.

Experimental studies provide strong evidence that the tumor microenvironment is immunosuppressive. Central to this activity are the macrophages that abundantly populate the tumors of both mice and women. Using a mouse model for breast cancer, the researchers have developed a transgenic strain that allows them to specifically measure and manipulate immune responses. They will measure changes in immune response when macrophages are removed and determine the mechanism that tumors use to prevent immune rejection.

Defining the mechanisms of immune suppression in breast cancer will pave the way for new therapeutic targets, particularly those associated with mononuclear phagocytic cells whose inhibition will allow the immune system the freedom to attack tumor cells.

**Xiaojing Ma, PhD**, Weill Cornell Medical College, "Targeting CCL5 in Triple Negative Breast Cancer," 1/1/13 – 12/31/14, \$360,000.

Breast cancer is a leading cause of mortality among women in the Western world. Some types of triple negative breast cancer are especially aggressive.

Recent clinical work demonstrates that a blood-borne molecule called CC chemokine ligand 5 (CCL5) is strongly associated with the progression of triple negative breast cancer. How CCL5 contributes to the development of triple negative breast cancer is poorly understood. The researcher's recent experimental work in animal models has shown that the principal way by which CCL5 promotes triple negative breast cancer growth is to generate a special population of immunosuppressive cells in the bone marrow called myeloid-derived suppressive cells (MDSCs), which infiltrate tumors, inhibit immune responses and help tumor progression. This study will further investigate the molecular details of how CCL5 helps generate the MDSCs in the bone marrow, and establish the procedure in which CCL5 in the bone marrow can be targeted via state of the art nanoparticle technology.

#### Program Outreach and Visibility

The HRSB/Program website at: <a href="http://www.wadsworth.org/breastcancer">http://www.wadsworth.org/breastcancer</a> continues to be improved to make it more descriptive and easier to search. Updated reference materials have been placed on the web to assist researchers and administrators with contract compliance, progress reporting and fiscal management.

An e-Alert feature allows interested parties to receive notification of Board activities such as RFA issuances, event announcements, news releases and awards made. Ongoing improvements to this communication tool for potential applicants, contractors and the general public are expected to increase interest in, support for, and visibility of the program.

#### Peer Review

The Department of Health uses a contractor to manage the independent scientific and technical merit peer-review process for evaluating applications for funding. The external peer-review process is intended to:

- remove Board and staff members from the peer review process, reducing the perception of possible conflicts of interest;
- obtain the highest quality review of applications; and
- allow independent peer reviews in a timely manner by expert scientists, clinicians, educators and advocates.

#### Pesticide-Related Activities

#### Pesticide Data Collection and Access

Confidential information from the Pesticide Sales and Use Reporting Database (also known as the Pesticide Registry or PSUR) collected by the DEC and pesticide application information maintained by private applicators are, with certain restrictions, available to scientists involved in

human health-related research. Any information, such as a name and address that could identify a commercial or private pesticide applicator, including a farmer or anyone who receives the services of a commercial applicator, is considered confidential. Researchers seeking confidential pesticide registry information or pesticide application information can access pertinent documents at <a href="http://www.health.state.ny.us/environmental/pesticide/reporting/">http://www.health.state.ny.us/environmental/pesticide/reporting/</a> or by contacting the DOH toll-free at 1(800) 458-1158, extension 2-7950. The following researcher access documents will be provided: Request for Pesticide Registry or Pesticide Application Information; Guidelines to Restrict the Dissemination by Researchers of Confidential Pesticide Registry and Pesticide Application Information; Agreement to Maintain Confidentiality; and an information sheet that summarizes these documents in lay language.

Committee on Access to Pesticide Registry and Pesticide Application Information. The Board is charged with reviewing requests for access to the confidential pesticide information collected pursuant to Sections 33-1203 and 33-1205 of the ECL. The Board's bylaws designate the Committee on Access to Pesticide Registry and Pesticide Application Information as one of its standing committees. The committee is responsible for reviewing requests for pesticide registry and pesticide application information for use in human health-related research projects. The committee makes recommendations to the full Board for final action. The entire review process requires four to six months.

No new applications were received from researchers during 2011-2012 for use of the confidential pesticide sales and use data in human health-related studies.

## <u>Evaluation of the Basis, Efficiency and Scientific Utility of the Information Derived From Pesticide Reporting</u>

The statute requires that this report include, "...an evaluation... of the basis, efficiency and scientific utility of the information derived from pesticide reporting," as well as recommendations as to "...whether such system should be modified or continued." Information on pesticide reporting has been gathered from interested parties through surveys conducted between 2000 and 2010 that were mailed, e-mailed, or posted on relevant websites. Respondents were asked how they were using the pesticide data and how the data could be made more useful to them. Although the surveys did not have good response rates, some information on how the pesticide data have been used was obtained, and many suggestions on improving the dataset were received. A summary of this information follows.

The pesticide sales and use data have been used primarily for the following:

- Targeting areas for water quality assessment;
- Answering questions from the public or organizations about pesticide use; and
- Determining patterns of pesticide use for mapping, development of education programs for farmworker safety and health, and targeting pesticide use reduction, less toxic alternatives, or integrated pest management.

Many suggestions for changes to the database have been made by survey respondents, and changes have been made to improve the efficiency of the database and to make it easier to access the data. Some of the suggested revisions would require a change in legislation. Appendix XII includes the Board's recommendations on pesticide reporting based on comments made by users of the data and interested parties through 2010. Summaries of progress achieved to date are also included.

Some of the major changes that have been made to the database include:

expressing quantities by pounds of active ingredient as well as amount of pesticide product

- increasing the percentage of data electronically reported
- developing computer programs for quality control and
- modifying the website for improving searching capabilities.

#### <u>Board Reports on Pesticide-Related Topics and on Studies Using or Referring to the Pesticide</u> Sales and Use Database

The Board has released the following reports on pesticide-related topics since its inception. The Legislative mandates for the reports are noted in brackets:

- Data Sets Collected and Maintained by New York State Government that May Assist Researchers Engaged in Breast, Prostate or Testicular Cancer Research, January 1999 [PHL Section 2412(a) and (b)]
- Pesticide Use and Pesticide Exposure, May 1999 [PHL §2411(1)(f)]
- Reference List: Pesticide Use and Pesticide Exposure, May 1999 [PHL §2411(1)(f)]
- Reference List: Pesticide Use and Pesticide Exposure, September 2002 [PHL §2411(1)(f)]
- Comparison of Pesticide Reporting and Pesticide Use, February 2000 [PHL §2411(1)(g)]
- Survey Results and Recommendations Pesticide Reporting Law, February 2001 [PHL §2413]
- Results of the 2002-2003 Survey on Pesticide Reporting and Board Recommendations, March 2005 [PHL §2413]
- Household Pesticide Use Report to the Health Research Science Board, June 2009 [PHL §2413]

Copies of these reports or information about the Board's pesticide-related activities may be obtained by calling the DOH toll-free at 1(800) 458-1158, extension 2-7950.

The Board recommended in 2004 that each biennial report should include references to studies that have been stimulated or influenced by the pesticide database. During 2011-2012, two articles were published.

#### Research study from user of the pesticide sales and use database

Richards BK, Pacenka S, Salvucci AE, Saia SM, Whitbeck LF, Furdyna PM and Steenhuis TS. Surveying Upstate NY Well Water for Pesticide Contamination: Cayuga and Orange Counties. Groundwater Monitor Remed 32:73-82, 2012.

#### Research study referring to the pesticide sale and use database

Horton MK, Jacobson JB, McKelvey W, Holmes D, Fincher B, Quantano A, Diaz BP, Shabbazz F, Shepard P, Rundle A and Whyatt RM. Characterization of Residential Pest Control Products Used in Inner City Communities in New York City. J Expo Sci Environ Epidemiol 21:291-301, 2011.

A list of seventeen publications arising from studies that used the Pesticide Sales and Use Reporting Database, and publications referring to the database, is provided in Appendix XIII.

#### VI. CONCLUSION

A number of exciting scientific and education breast cancer research projects are underway, supported by the Breast Cancer Research and Education Fund. The Board is grateful for taxpayer gifts to the Fund and for the State matching of these gifts that enables the Board to facilitate advances in the fight against breast cancer.

The Board projects that DOH will be able to issue a scientific research and an education research RFA annually. Issuance of RFAs at the same time each year is planned for consistent expenditures of the Breast Cancer Research and Education Fund. Standardized issuance of RFAs will also provide successful applicants with consistent contract start dates for ease of management of their laboratories, programs, resources and funds.

The Board looks forward to continued progress and success in achieving its mandates to support critical research and education projects while simultaneously stimulating economic development within New York.

# Appendices I - XIII and Abbreviation Key

#### APPENDIX I

#### PUBLIC HEALTH LAW

#### ARTICLE 24, TITLE 1-B HEALTH RESEARCH SCIENCE BOARD

As amended by Chapter 32 of the Laws of New York, 2008

Section 2410. Health research science board.

Section 2411. Powers and duties of the board.

Section 2412. Agency implementation.

Section 2413. Biennial report.

#### § 2410. Health research science board.

- 1. There is hereby established in the department the health research science board. The board shall be comprised of seventeen voting members, three non-voting regional members and three non-voting ex-officio members as follows:
  - (a) twelve voting members shall be scientists each of whom shall have either an M.D., D.O., Ph.D., or Dr.P.H. in one of the following fields: biochemistry, biology, biostatistics, chemistry, epidemiology, genetics, immunology, medicine, microbiology, molecular biology, nutrition, oncology, reproductive endocrinology, or toxicology and must currently be engaged in treating patients or conducting health research. Such members shall be appointed in the following manner: two shall be appointed by the temporary president of the senate and one by the minority leader of the senate; two shall be appointed by the speaker of the assembly and one by the minority leader of the assembly; six shall be appointed by the governor;
  - (b) the governor shall appoint six regional members, three of whom shall serve as full voting members and three of whom shall serve as alternative members without voting rights. Such regional members shall be persons who have or have had breast cancer, and shall be actively involved with a community-based, grass-roots breast cancer organization. Two of such appointments shall be made upon the recommendation of the temporary president of the senate and two shall be made upon the recommendation of the speaker of the assembly. One regional member shall be appointed from each of the following geographic areas of the state: Long Island, New York City, the Hudson Valley, Northern New York, Central New York and Western New York. The order of appointments and recommendations for appointments and voting rights shall rotate as follows:
    - (i) The governor shall appoint regional members for three year terms in the following order:
      - (A) Long Island, which member shall have voting rights,
      - (B) Central New York, which member shall not have voting rights,
      - (C) Hudson Valley, which member shall have voting rights,
      - (D) Northern New York, which member shall not have voting rights.
      - (E) Western New York, which member shall have voting rights, and
      - (F) New York City, which member shall not have voting rights;
    - (ii) The governor, upon the recommendation of the temporary president of the senate, shall appoint regional members for three year terms in the following order:
      - (A) Hudson Valley, which member shall not have voting rights,
      - (B) Northern New York, which member shall have voting rights,

- (C) Western New York, which member shall not have voting rights,
- (D) New York City, which member shall have voting rights,
- (E) Long Island, which member shall have voting rights, and
- (F) Central New York, which member shall not have voting rights; and
- (iii) The governor, upon the recommendation of the speaker of the assembly, shall appoint regional members for three year terms in the following order:
  - (A) Western New York, which member shall have voting rights,
  - (B) New York City, which member shall not have voting rights,
  - (C) Long Island, which member shall not have voting rights,
  - (D) Central New York, which member shall have voting rights,
  - (E) Hudson Valley, which member shall not have voting rights, and
  - (F) Northern New York, which member shall have voting rights;
- (c) The governor shall appoint three non-voting ex officio members to the board, one of whom shall be the commissioner, or his or her designee, one of whom shall be the commissioner of environmental conservation, or his or her designee, and one of whom shall be the director of the Cornell University Institute for Comparative and Environmental Toxicology, or his or her designee; and
- (d) The governor shall appoint one voting member who shall be a person who has or has survived breast cancer and one voting member who shall be a person who has or has survived prostate or testicular cancer. The governor shall designate the chair of the board. The governor, temporary president of the senate, minority leader of the senate, speaker of the assembly, and minority leader of the assembly may solicit recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, the Federal Agency For Health Care Policy and Research, and the National Academy of Sciences for appointments or recommendations for appointments to the board.
- 2. All members shall serve for terms of three years and may be reappointed, such terms to commence July first and expire June thirtieth; provided, however, that of the scientific members first appointed, three such members, one appointed by the governor, one appointed by the temporary president of the senate and one appointed by the speaker of the assembly, shall be appointed by the temporary president of the senate, and one appointed by the speaker of the assembly shall be appointed for a term of two years.

The board shall convene on or before September first, nineteen hundred ninety-seven.

- 3. Any member, after notice and an opportunity to be heard, may be removed by the governor for neglect of duty or malfeasance in office. Any member who fails to attend three consecutive meetings of the board, unless excused by formal vote of the board, shall be deemed to have vacated his or her position.
- 4. Any vacancy in the board shall be filled for the unexpired term in the same manner as the original appointment.
- 5. A majority of the voting members of the board shall constitute a quorum for the transaction of any business or the exercise of any power or function of the board.
- 6. Members of the board shall not receive compensation for their services as members, but shall be allowed their actual and necessary expenses incurred in the performance of their duties.

- 7. For the purposes of this section the following counties shall constitute the following geographic areas:
  - (a) Long Island: the counties of Nassau and Suffolk.
  - (b) New York City: the counties of Kings, Queens, Richmond, New York and Bronx.
  - (c) Hudson Valley: the counties of Westchester, Rockland, Putnam, Orange, Dutchess, Ulster, Greene, Columbia, Sullivan and Delaware.
  - (d) Northern New York: the counties of Albany, Clinton, Essex, Franklin, Fulton, Herkimer, Hamilton, Montgomery, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, Warren and Washington.
  - (e) Central New York: the counties of Broome, Cayuga, Chemung, Chenango, Cortland, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, Seneca, Schuyler, St. Lawrence, Tioga, Tompkins and Wayne.
  - (f) Western New York: the counties of Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, Wyoming, Livingston, Monroe, Ontario, Steuben and Yates.

#### § 2411. Powers and duties of the board.

- 1. The board shall:
  - (a) Survey state agencies, boards, programs and other state governmental entities to assess what, if any, relevant data has been or is being collected which may be of use to researchers engaged in breast, prostate or testicular cancer research;
  - (b) Consistent with the survey conducted pursuant to paragraph (a) of this subdivision, compile a list of data collected by state agencies which may be of assistance to researchers engaged in breast, prostate or testicular cancer research as established in section twentyfour hundred twelve of this title;
  - (c) Consult with the Centers for Disease Control and Prevention, the National Institutes of Health, the Federal Agency For Health Care Policy and Research, the National Academy of Sciences and other organizations or entities which may be involved in cancer research to solicit both information regarding breast, prostate and testicular cancer research projects that are currently being conducted and recommendations for future research projects;
  - (d) Review requests made to the commissioner for access to information pursuant to paragraph b of subdivision one of section 33-1203 and paragraph c of subdivision two of section 33-1205 of the environmental conservation law for use in human health related research projects. Such data shall only be provided to researchers engaged in human health related research. The request made by such researchers shall include a copy of the research proposal or the research protocol approved by their institution and copies of their institution's Institutional Review Board (IRB) or equivalent review board approval of such proposal or protocol. In the case of research conducted outside the auspices of an institution by a researcher previously published in a peer-reviewed scientific journal, the board shall request copies of the research proposal and shall deny access to the site-specific and nine-digit zip code pesticide data if the board determines that such proposal does not follow accepted scientific practice for the design of a research project. The board shall establish guidelines to restrict the dissemination by researchers of the name, address or other information that would otherwise identify a commercial applicator or private applicator or any person who receives the services of a commercial applicator:

- (e) Solicit, receive, and review applications from public and private agencies and organizations and qualified research institutions for grants from the breast cancer research and education fund, created pursuant to section ninety-seven-yy of the state finance law, to conduct research or educational programs which focus on the causes, prevention, screening, treatment and cure of breast cancer and may include, but are not limited to basic, behavioral, clinical, demographic, environmental, epidemiologic and psychosocial research. The board shall make recommendations to the commissioner, and the commissioner shall, in his or her discretion, grant approval of applications for grants from those applications recommended by the board. The board shall consult with the Centers for Disease Control and Prevention, the National Institutes of Health, the Federal Agency For Health Care Policy and Research, the National Academy of Sciences, breast cancer advocacy groups, and other organizations or entities which may be involved in breast cancer research to solicit both information regarding breast cancer research projects that are currently being conducted and recommendations for future research projects. As used in this section, "qualified research institution" may include academic medical institutions, state or local government agencies, public or private organizations within this state, and any other institution approved by the department, which is conducting a breast cancer research project or educational program. If a board member submits an application for a grant from the breast cancer research and education fund, he or she shall be prohibited from reviewing and making a recommendation on the application;
- (f) Consider, based on evolving scientific evidence, whether a correlation exists between pesticide use and pesticide exposure. As part of such consideration the board shall make recommendations as to methodologies which may be utilized to establish such correlation;
- (g) After two years of implementation of pesticide reporting pursuant to section 33-1205 of the environmental conservation law, the board shall compare the percentage of agricultural crop production general use pesticides being reported to the total amount of such pesticides being used in this state as estimated by Cornell University, Cornell Cooperative Extension, the department of environmental conservation, and the Environmental Protection Agency;
- (h) Meet at least six times in the first year, at the request of the chair and at any other time as the chair deems necessary. The board shall meet at least four times a year thereafter. Provided, however, that at least one such meeting a year shall be a public hearing, at which the general public may question and present information and comments to the board with respect to the operation of the health research science board, the breast cancer research and education fund, the prostate and testicular cancer research and education fund and pesticide reporting established pursuant to sections 33-1205 and 33-1207 of the environmental conservation law. At such hearing, the commissioner of the department of environmental conservation or his or her designee shall make a report to the board with respect to the efficiency and utility of pesticide reporting established pursuant to sections 33-1205 and 33-1207 of the environmental conservation law.
- 2. The commissioner shall request that the department of environmental conservation compile information pursuant to paragraph b of subdivision one of section 33-1203 of the environmental conservation law as necessary to fulfill board approved requests, pursuant to paragraph (d) of subdivision one of this section.
- 3. The commissioner shall provide the board with such staff assistance and support services as are necessary for the board to perform the functions required of it under this section.

#### § 2412. Agency implementation.

All state agencies, including, but not limited to, the departments of agriculture and markets, environmental conservation, and health, shall review their programs and operations (pursuant to guidelines established by the board) to determine whether they currently collect data which may be of use to researchers engaged in breast, prostate or testicular cancer research. Any agency collecting such data shall forward a description of the data to the health research science board.

#### § 2413. Biennial report.

The commissioner shall submit a report on or before January first commencing in nineteen hundred ninety-nine, and biennially thereafter, to the governor, the temporary president of the senate and the speaker of the assembly concerning the operation of the health research science board. Such report shall include recommendations from the health research science board including, but not limited to, the types of data that would be useful for breast, prostate or testicular cancer researchers and whether private citizen use of residential pesticides should be added to the reporting requirements. The report shall also include a summary of research requests granted or denied. In addition, such report shall include an evaluation by the commissioner, the commissioner of the department of environmental conservation and the health research science board of the basis, efficiency and scientific utility of the information derived from pesticide reporting pursuant to sections 33-1205 and 33-1207 of the environmental conservation law and recommend whether such system should be modified or continued. The report shall include a summary of the comments and recommendations presented by the public at the board's public hearings.

#### **APPENDIX II**

# ENVIRONMENTAL CONSERVATION LAW TITLE 7: REGISTRATION OF PESTICIDES TITLE 12: PESTICIDE SALES AND USE DATA BASE AND RECORDKEEPING AND REPORTING

Section 33-0714. Water quality monitoring for pesticides.

Section 33-1201. Pesticide sales and use computer data base.

Section 33-1203. Access to pesticide information.

Section 33-1205. Record keeping and reporting.

Section 33-1207. Record keeping and reporting by importers and manufacturers.

#### § 33-0714. Water quality monitoring for pesticides.

The department, in coordination with the United States Geological Survey, National Water Quality Assessment Program, the New York State Water Resources Institute, and other parties, shall conduct a water quality monitoring program to provide an adequate understanding of the health and environmental impacts of pesticide use in the state. The department shall utilize this program, as it deems necessary, in: making pesticide registration decisions; reviewing suspensions and cancellations of pesticide registrations in the state; and assessing the status, trends, and health impacts of any pesticide contamination of ground and surface waters on Long Island and throughout the state.

#### § 33-1201. Pesticide sales and use computer data base.

- (a) The department shall develop a pesticide sales and use computer data base in conjunction with Cornell University. The data base shall be maintained at the department.
  - (b) Such data base shall consist of all information compiled from reports submitted to the department pursuant to sections 33-1205 and 33-1207 of this title. Such reports shall be entered into and maintained on a computerized data base and shall be updated annually. Information obtained for and contained in the data base shall be accessible by interested parties only to the extent permitted pursuant to the provisions of subdivision two of this section and paragraph a of subdivision 1 of section 33-1203 of this title.
- 2. The commissioner shall prepare an annual report summarizing pesticide sales, quantity of pesticides used, category of applicator and region of application. The commissioner shall not provide the name, address, or any other information which would otherwise identify a commercial or private applicator, or any person who sells or offers for sale restricted use or general use pesticides to a private applicator, or any person who received the services of a commercial applicator. In accordance with article six of the public officers law, proprietary information contained within such record, including price charged per product, shall not be disclosed. The report shall be submitted to the governor, the temporary president of the senate and the speaker of the assembly, and shall be made available to all interested parties. The first report shall be submitted on July first, nineteen hundred ninety-eight and on July first annually thereafter.

#### § 33-1203. Access to pesticide information.

- 1. (a) The commissioner shall, upon written request of an interested party, in printed form or on a diskette in computerized data base format, provide the information on pesticides submitted to the department pursuant to sections 33-1205 and 33-1207 of this title. Such information shall be provided by county or counties, or five-digit zip code or codes as selected by the interested party making the written request. The commissioner shall not provide the name, address, or any other information which would otherwise identify a commercial or private applicator, or any person who sells or offers for sale restricted use or general use pesticides to a private applicator, or any person who received the services of a commercial applicator. In accordance with article six of the public officers law, proprietary information contained within such record, including price charged per product, shall not be disclosed. The provisions of this paragraph shall not apply to the provision of pesticide data to the commissioner of health, the health research science board and researchers pursuant to title one-B of article twenty-four of the public health law.
  - (b) The department shall, upon request from the department of health, compile pesticide application information by nine-digit zip code and provide the information to the commissioner of health for researchers entitled to receive information pursuant to paragraph (d) of subdivision one of section twenty-four hundred eleven of the public health law provided, however, if the nine-digit zip code cannot be determined, the information shall be compiled by town or city.
- 2. The fees for copies of information shall not exceed twenty-five cents per photocopy not in excess of nine inches by fourteen inches, or the actual cost of reproducing any information.

#### § 33-1205. Recordkeeping and reporting.

- 1. All commercial applicators shall maintain pesticide use records for each pesticide application containing the following:
  - (a) EPA registration number;
  - (b) product name;
  - (c) quantity of each pesticide used;
  - (d) date applied;
  - (e) location of application by address (including five-digit zip code).

Such records shall be maintained for a period of not less than three years. All commercial applicators shall file, at least annually, a report or reports containing such information with the department on computer diskette or in printed form on or before February first for the prior calendar year. All commercial applicators shall also maintain corresponding records of the dosage rates, methods of application and target organisms for each pesticide application. These records shall be maintained on an annual basis and retained for a period of not less than three years and shall be available for inspection upon request by the department.

2. (a) Every person who sells or offers for sale restricted use pesticides to private applicators shall issue a record to the private applicator of each sale of a restricted use pesticide or a general use pesticide used in agricultural crop production to such applicator. Such record of each sale shall include the following:

- (1) EPA registration number;
- (2) product name of the pesticide purchased;
- (3) quantity of the pesticide purchased;
- (4) date purchased;
- (5) location of intended application by address (including five-digit zip code) or if address is unavailable by town or city (including five-digit zip code) if the location of intended application differs from the billing address that appears on the record.

Every person who sells or offers for sale restricted use pesticides to private applicators shall file, at least annually, a report or reports containing such information with the department on computer diskette or in printed form on or before February first for the prior calendar year. The department shall not use the reports filed pursuant to this paragraph for enforcement purposes.

- (b) All private applicators shall maintain, at a minimum, records of the restricted pesticides purchased, crop treated by such, method of application, and date of application or applications. This information shall be maintained on an annual basis and retained for a minimum of three years, and shall be available for inspection upon request by the department.
- (c) A private applicator shall, upon request, within six months, provide site-specific information relating to pesticide applications to any researcher entitled to receive information pursuant to paragraph (d) of subdivision one of section twenty-four hundred eleven of the public health law, provided, however, such request shall not be granted during planting and harvesting unless at a time and in a manner that is mutually convenient.
- § 33-1207. Recordkeeping and reporting by importers and manufacturers.
- 1. Each person manufacturing or compounding a registered restricted use pesticide in this state, or importing or causing a registered restricted use pesticide to be imported into this state for use, distribution, or storage, shall maintain records of all sales within the state during the preceding year of each restricted use pesticide product which he or she has imported, manufactured or compounded. The record of each restricted use pesticide product shall include:
  - (a) EPA registration number;
  - (b) container size; and
  - (c) number of containers sold to New York purchasers.
- 2. Such records shall be maintained for a period of not less than three years. All manufacturers and importers shall file an annual report containing such information with the department on computer diskette or in printed form on or before February first for the prior calendar year.

#### APPENDIX III

## STATE FINANCE LAW ARTICLE 6

§ 97-yy. Breast cancer research and education fund.

- 1. There is hereby established in the joint custody of the commissioner of taxation and finance and the comptroller, a special fund to be known as the "breast cancer research and education fund".
- 2. Such fund shall consist of all revenues received by the department of taxation and finance, pursuant to the provisions of section two hundred nine-D and section six hundred twenty-seven of the tax law, all moneys collected pursuant to section four hundred four-q of the vehicle and traffic law, and all other moneys appropriated, credited, or transferred thereto from any other fund or source pursuant to law. For each state fiscal year, there shall be appropriated to the fund by the state, in addition to all other moneys required to be deposited into such fund, an amount equal to the amounts of monies collected and deposited into the fund pursuant to sections two hundred nine-D and six hundred twenty-seven of the tax law and section four hundred four-q of the vehicle and traffic law during the preceding calendar year, as certified by the comptroller. Nothing contained herein shall prevent the state from receiving grants, gifts or bequests for the purposes of the fund as defined in this section and depositing them into the fund according to law.
  - (a) On or before the first day of February each year, the comptroller shall certify to the governor, temporary president of the senate, speaker of the assembly, chair of the senate finance committee and chair of the assembly ways and means committee, the amount of money deposited in the breast cancer research and education fund during the preceding calendar year as the result of revenue derived pursuant to sections two hundred nine-D and six hundred twenty-seven of the tax law and section four hundred four-q of the vehicle and traffic law.
- 3. Monies of the fund shall be expended only for breast cancer research and educational projects. As used in this section, "breast cancer research and education projects" means scientific research or educational projects which, pursuant to section two thousand four hundred eleven of the public health law, are approved by the department of health, upon the recommendation of the health research science board.
- 4. Monies shall be payable from the fund on the audit and warrant of the comptroller on vouchers approved and certified by the commissioner of health.
- 5. To the extent practicable, the commissioner of health shall ensure that all monies received during a fiscal year are expended prior to the end of that fiscal year.

#### APPENDIX IV

# STATE TAX LAW ARTICLE 9-A

§ 209-D. Gift for breast cancer research and education. Effective for any tax year commencing on or after January first, nineteen hundred ninety-six, a taxpayer in any taxable year may elect to contribute to the support of the breast cancer research and education fund. Such contribution shall be in any whole dollar amount and shall not reduce the amount of the state tax owed by such taxpayer. The commissioner shall include space on the corporate income tax return to enable a taxpayer to make such contribution. Notwithstanding any other provision of law, all revenues collected pursuant to this section shall be credited to the breast cancer research and education fund and shall be used only for those purposes enumerated in section ninety-sevenyy of the state finance law.

#### **ARTICLE 22, PART 2**

§ 627. Gift for breast cancer research and education. Effective for any tax year commencing on or after January first, nineteen hundred ninety-six, an individual in any taxable year may elect to contribute to the breast cancer research and education fund. Such contribution shall be in any whole dollar amount and shall not reduce the amount of state tax owed by such individual. The commissioner shall include space on the personal income tax return to enable a taxpayer to make such contribution. Notwithstanding any other provision of law all revenues collected pursuant to this section shall be credited to the breast cancer research and education fund and used only for those purposes enumerated in section ninety-seven-yy of the state finance law.

#### APPENDIX V

# VEHICLE AND TRAFFIC LAW TITLE 4, ARTICLE 14

- \* § 404-q. Distinctive "drive for the cure" license plates.
- 1. Any person residing in this state shall, upon request, be issued a distinctive "drive for the cure" license plate in support of breast, prostate and testicular cancer research bearing the phrase "drive for the cure". Application for said license plate shall be filed with the commissioner in such form and detail as the commissioner shall prescribe.
- 2. A distinctive "drive for the cure" license plate issued pursuant to this section shall be issued in the same manner as other number plates upon the payment of the regular registration fee prescribed by section four hundred one of this article, provided, however, that an additional annual service charge of twenty-five dollars shall be charged for such plate. Twelve dollars and fifty cents from each twenty-five dollars received as annual service charges under this section shall be deposited to the credit of the breast cancer research and education fund established pursuant to section ninety-seven-yy of the state finance law and shall be used for research and education programs undertaken pursuant to section twenty-four hundred ten of the public health law. Twelve dollars and fifty cents from each twenty-five dollars received as annual service charges under this section shall be deposited to the credit of the prostate and testicular cancer research and education fund established pursuant to section ninety-sevenccc of the state finance law and shall be used for research and education programs undertaken pursuant to section ninety-seven-ccc of the state finance law. Provided, however that one year after the effective date of this section funds in the amount of six thousand dollars, or so much thereof as may be available, shall be allocated to the department to offset costs associated with the production of such license plates.

#### APPENDIX VI

#### **HEALTH RESEARCH SCIENCE BOARD BYLAWS**

#### I. CHAIRPERSON

The Chairperson of the Health Research Science Board ("Board") shall be designated by the Governor. The Chairperson shall perform the duties ordinarily associated with that office. The Chairperson shall have responsibility for the general supervision of the work of the Board. He or she shall have the power, unless the Board shall have provided for other representation, to represent the Board before the Governor, committees of the Legislature, or other public authorities, and may request any member or members to appear with him or her in his or her stead. The Chairperson shall preside at Board meetings. In the absence of the Chairperson from any meeting, the Board may elect one of its members to preside during such absence.

#### II. CODE OF ETHICS

Members of the Board shall comply with Section 74 (Code of Ethics) of the Public Officers Law. No member of the Board should have any interest, financial or otherwise, direct or indirect, or engage in any business, transaction, or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his or her duties as a Board member. Members should exercise their duties and responsibilities as Board members in the public interest of the inhabitants of the State, regardless of their affiliation with, or relationship to, any facility, agency, program, activity, category of provider, or interest group. The principles that should guide the conduct of Board members include, but are not limited to, the following:

- a) A Board member should endeavor to pursue a course of conduct that will not raise suspicion among the public that he or she is likely to be engaged in acts that are in violation of his or her trust as a Board member.
- b) No Board member should permit his or her employment to impair his or her independence of judgment in the exercise of his or her duties as a Board member.
- c) No Board member should disclose confidential information acquired by him or her in the course of his or her duties as a Board member, or by reason of his or her position as a Board member, nor use such information to further his or her personal interests.
- d) No Board member should use, or attempt to use, his or her position as a Board member to secure unwarranted privileges or exemptions for himself or herself or others.
- e) No Board member should engage in any transaction as a representative or agent of the State with any business entity in which he or she has a direct or indirect financial interest that might reasonably tend to conflict with the proper discharge of his or her duties as a Board member.
- f) A Board member should refrain from making personal investments in enterprises which he or she has reason to believe may be directly involved in decisions to be made by him or her as a Board member or which will otherwise create substantial conflict between his or her duty as a Board member to act in the public interest and his or her private interest.

#### III. CONFLICT OF INTEREST

<u>Section 1.</u> Pending Applications and Requests. This section applies both to activities of the full Board and activities of committees of the Board.

- a) Absolute Disqualifications. When a Board member, or a member of a committee who is not a Board member, submits an application for a grant from the Breast Cancer Research and Education Fund, under Section 2411(1)(e) of the Public Health Law, or a request for access to Pesticide Registry or pesticide application information, under Section 2411(1)(d) of the Public Health Law, or a Board member, or a member of a committee who is not a Board member, or his or her family has an interest, financial or otherwise, whether as owner, officer, director, fiduciary, employee, consultant or supplier of goods or services regarding a facility, agency or program or activity whose application for a grant from the Breast Cancer Research and Education Fund, under Section 2411(1)(e) of the Public Health Law, or whose request for access to Pesticide Registry or pesticide application information, under Section 2411(1)(d) of the Public Health Law, is before the Board or a committee of the Board for consideration or determination, that member shall (i) identify such interest to the Board or committee at any meeting when the application or request is to be considered, (ii) absent himself, or herself, from any portion of any meeting when such application or request is considered, and (iii) not participate in any vote of the Board or committee on such application or request. For purposes of this Article, "family" shall include a spouse, children and any relative living in the member's household.
- b) Disclosure and Possible Disqualification. When a Board member, or a member of a committee who is not a Board member, or his or her family has (i) any of the above-noted interests in a facility, agency, program or activity, the status of which might reasonably be affected by another facility, agency, program or activity whose grant application or request for access to Pesticide Registry or pesticide application information is before the Board or a committee of the Board, or (ii) when a member has any other interest or association which might reasonably be construed as tending to embarrass the Board or elicit public suspicion that he or she might be engaged in acts in violation of his or her trust as a Board member, he or she shall, at the time of formal consideration of such application or request by the Board or committee, disclose such interest or association so that the Chairperson and, if necessary, the Board or committee can then determine whether his or her participation in the discussion of such application or request or the vote of the Board or committee thereon would be proper.
- c) Procedure. After a motion is made concerning a grant application or request for access to Pesticide Registry or pesticide application information and prior to discussion or vote, and at the request of the Chairperson, the Board members and members of committees who are not Board members, shall disclose all actual or potential conflicts and, when appropriate, explain the conflicts. In the case of conflicts constituting Absolute Disqualifications, the members with such conflicts shall immediately leave the meeting and remain absent during the period when the application or request is under consideration. In the case of conflicts constituting Possible Disqualifications, the Chairperson shall rule upon such conflicts subject to appeal by motion to the Board or committee that may override the Chairperson's decision by the affirmative vote of a majority of those present, excluding those members who are the subject of the vote.

d) Compliance with Public Officers Law. Members of the Board shall comply with Sections 74 and 78 of the Public Officers Law as amended and the following rules governing conflicts of interest: (i) No member shall receive compensation in return for services rendered in relation to matters before any State agency if compensation is contingent upon action or failure to act by such State agency, (ii) no member of the Board who is also associated with any firm or association in which he/she has a specific interest shall sell any goods or services valued in excess of \$25 to any State agency unless pursuant to competitive bid, (iii) no member of the Board shall accept any gift (in excess of \$75) under circumstances in which it could reasonably be inferred that the gift was intended to influence him/her as a member of the Board, (iv) members of the Board shall avoid any action which might result in or create the appearance of a conflict of interest.

# Section 2. Pending Matters-Committees.

- a) **Disclosure at Committee Meetings.** When a member of a committee of the Board or his or her family has any of the interests noted in Section 1(a) of this Article in a facility, program or activity the status of which might reasonably be affected by a matter which is before the committee, or when a member has an interest or association which might reasonably be construed as tending to embarrass the Board or committee or elicit public suspicion that he or she might be engaged in acts in violation of his or her trust, he or she shall, at the time of formal consideration of such matter by the committee, disclose such interest or association to the committee so that the committee is fully aware of such member's interest or association. A committee member who discloses such interest or association may, but shall not be required to, abstain from participation in the discussion of or vote on such matter at the committee meeting, unless a member is absolutely disqualified from voting in accordance with Section 1(a) of this Article.
- b) **Disclosure at Board Meetings.** When the Chairperson of any committee which considered a matter reports the Committee's deliberations and recommendations to the Board, the Committee Chairperson shall indicate in the report all interests or associations disclosed by the committee members and state how such members voted with respect to the committee's recommendations. A committee member who disclosed such interest or association may, but shall not be required to, abstain from participation in the discussion of or vote on such matter at the Board meeting, unless a member is absolutely disqualified from voting in accordance with Section 1(a) of this Article.
- c) **Violation of Provisions.** If any member knowingly and intentionally violates these provisions, the Board or its chairperson shall refer the matter to the Commissioner of Health for appropriate action.

# IV. DESIGNATION AND DUTIES OF THE SECRETARY

The Board shall request the Department of Health to designate a Department employee as the Board's Secretary.

The Secretary shall prepare and send official notices of actions of the Board and shall administer the daily business of the Board under the general direction of the Chairperson. The Secretary shall send a copy of the Minutes of each meeting of the Board to each member of the Board as soon as practicable after the meeting. The Minutes, as approved or corrected, shall serve as the official record of a meeting of the Board. Minutes shall be distributed or made

available to the public after they have been approved by the Board. The Secretary shall make available records requested under the Freedom of Information Law and make announcements to the media and public of scheduled meetings as required by the Open Meetings Law.

#### V. MEETINGS OF THE BOARD

- a) The regular meetings of the Board shall be held at least six times during the first year subsequent to December 1, 1997, and at least four times a year thereafter at a date, time and place approved by a majority of members, unless otherwise determined by the Board or by the Chairperson, who shall notify the Secretary at least ten business days in advance of the meeting. Special meetings of the Board may be called by the Chairperson at his or her discretion, or on the request of two members, and shall be called by the Chairperson on the written request of three members.
- b) At least one meeting each year shall be a public hearing at which the general public may question and present information and comments to the Board with respect to the operation of the Board, the Breast Cancer Research and Education Fund, the Prostate and Testicular Cancer Research and Education Fund and pesticide reporting established pursuant to Sections 33-1205 and 33-1207 of the Environmental Conservation Law. At the public hearing, the Commissioner of the Department of Environmental Conservation or his or her designee shall make a report to the Board with respect to the efficiency and utility of pesticide reporting established pursuant to Sections 33-1205 and 33-1207 of the Environmental Conservation Law.
- c) At least some portion of every regular Board meeting shall be set aside for public comment. A portion of one Board meeting each year shall be set aside for presentations of progress reports from selected award winners.
- The Secretary shall notify each Board member of Board meetings and shall send an agenda to his or her usual address not less than ten business days before the meeting.
  - 2) A majority of the voting members of the Board shall constitute a quorum for the transaction of any business or the exercise of any power or function of the Board and all matters requiring action shall be passed by a vote of a majority of the voting members of the Board. (A voting member abstaining from a vote shall be counted as present for the purpose of establishing a quorum.) Except as provided below, all meetings shall be conducted in accordance with Robert's Rules of Order Newly Revised, and a record of each vote shall be maintained. Non-voting ex officio members of the Board may make motions to be considered by the Board, but may not vote on these or any other motions before the Board. The normal method of voting shall be by roll call. A roll call vote on any question shall be taken by ayes and noes, abstentions noted, and a record of how each member voted entered in the Minutes.
  - 3) Any member who fails to attend three or more consecutive meetings or who fails to respond to three or more meeting availability inquiries shall be deemed to have vacated his or her position.
  - 4) Meetings of the Board shall be noticed and conducted in accordance with the requirements of Article 7 (Open Meetings Law) of the Public Officers Law. Such

meetings shall be open to the public except when otherwise provided by law. Guidelines for observers shall be adopted by the Board.

#### VI. ORDER OF BUSINESS

The order of business may be altered at the Chairperson's discretion or upon the request of a Board member.

A portion of each Board meeting shall be set aside for the development of an agenda for the next Board meeting.

# VII. PROPOSAL REVIEW PROCESS

# <u>Independent Scientific Review Panel</u>

There shall be one or more independent scientific review panels to review proposals (referred to as "applications for grants" in Public Health Law § 2411(1)(e)) for merit and to make recommendations to the Board for funding.

DOH staff, on behalf of the Board, will establish one or more independent scientific review panels, each of which shall be composed of at least one breast cancer survivor and/or activist, and one expert in breast cancer research and/or education. The number of independent scientific review panels will be dependent on the number of proposals received by the Board.

# Responsibilities of the Board

The Board shall consider and rank proposals considered by the independent scientific review panels. Following an affirmative vote of Board members, the Board shall recommend that the Commissioner of Health approve those proposals for which the Board determines that funding is available. Board or committee meetings, or portions thereof, at which Board or committee members consider, rank, discuss or vote on proposals received by the Board may be conducted in executive session as authorized by the Open Meetings Law.

# **Summary Report**

A summary report of the proposal review process will be prepared by Department of Health staff in consultation with the Board and made available to the public subsequent to the Board's recommendations to the Commissioner of Health.

# **Guidelines**

The Board shall adopt guidelines that will specify additional aspects of the proposal review process.

#### VIII. COMMITTEES

There shall be the following Standing Committees:

On oversight of the development of requests for proposals (grant applications), and the
process used to review proposals received by the Board; and on evaluating
breast/prostate/testicular cancer research and educational program effectiveness
nationwide and recommending future breast/prostate/testicular cancer research projects,
called the:

Committee on Program Needs and Effectiveness

2. On oversight and management of information requested by researchers from the New York State Department of Environmental Conservation Pesticide Sales and Use Registry and from private pesticide applicators called the:

Committee on Access to Pesticide Registry and Pesticide Application Information

3. On Breast Cancer Research and Education Fund contributions, and the Board's outreach activities, called the:

Committee on Funding and Outreach

Each Standing Committee shall consist of one or more members of the Board and may include non-Board members. The Chairperson of the Board shall appoint all Standing Committees and designate their Chairpersons. Duties of Standing Committees shall be prescribed by the Chairperson of the Board with approval by a majority of Board members.

In appointing Board members to any Standing Committee, the Chair shall, to the extent practicable, ensure that the Committee's composition reflects the overall composition of the Board and that any such Committee includes Board members and, if appropriate, non-Board members with relevant interests.

The Board may, at any time, provide for the appointment of a special committee on any subject. All such special committees not previously discharged by the Board shall be considered discharged one year following their appointment, unless the Board shall move to continue them.

A majority of the persons appointed to serve on a committee shall, if at least one Board member is present, constitute a guorum for the committee.

All committee matters requiring action or a formal recommendation shall be passed by a vote of a majority of the members appointed to serve on the committee.

When making a report to the Board, a committee should, in addition to reporting any recommendations of the majority of the committee, summarize any significant deliberations leading to such recommendations as well as opinions or recommendations of committee members who did not support the majority recommendations.

#### IX. OFFICE OF THE BOARD

The official headquarters of the Board (at which the official copies of its Minutes, records, documents and other papers shall be kept) shall be at the offices of the Commissioner of Health at Albany, New York. The Secretary shall be responsible for the safe-keeping of all Minutes, records, documents, correspondence and other items belonging to the Board. Every member of the Board and any other person duly authorized by a member shall have access at all times during the ordinary office hours of the Department of Health to all such Minutes, records, documents, correspondence and other items belonging to the Board; provided, however, that persons authorized by members shall not have access to records, documents, correspondence or other items that are exempt from disclosure or confidential under the Freedom of Information Law, the Personal Privacy Protection Law, or any other state or federal law. The Secretary shall designate some person to be in charge of all such Minutes, records, documents, correspondence and other items belonging to the Board during his or her absence from the office.

#### X. AMENDMENT OF BYLAWS

These Bylaws may be amended by the affirmative vote of the majority of the voting members of the Board at any regular or special meeting, provided that notice of the proposed amendment has been given at a prior meeting and that a copy of the proposed amendment has been sent by the Secretary to each member of the Board at least ten business days prior to the vote.

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#### **APPENDIX VII**

#### HEALTH RESEARCH SCIENCE BOARD MEMBERSHIP

# **Voting Members**

# SANTO M. DIFINO, MD, Chair

Dr. DiFino is a clinician with Hematology-Oncology Associates of Central New York, PC; Chief of Internal Medicine, St. Joseph's Hospital Health Center; and associate clinical professor, Department of Medicine, State University of New York (SUNY) Upstate Medical Center, Syracuse, New York (NY). He was elected to Phi Beta Kappa and earned a BS degree in biology, *magna cum laude*, from Fordham University. Dr. DiFino obtained his medical degree in 1974 from the New Jersey Medical School. He interned and completed a residency in medicine at the SUNY Upstate Medical Center, Syracuse. He is board-certified in internal medicine, medical oncology and hematology.

Dr. DiFino has been the Chair of Internal Medicine at St. Joseph's Health Center from 1984 to present. He was the principal investigator of the Syracuse Community Clinical Oncology Program from 1984 to 1994 and continues as associate investigator there. He is also a member of Cancer and Leukemia Group B. Dr. DiFino was president of the Central New York Chapter of the Leukemia Society of America from 1994 to 1996 and was recipient of the Leukemia Society's Man of the Half Century Award. As a result of his active involvement in community service, he was nominated as Health Citizen of the Year and is a recipient of the President's Medallion from Catholic Charities of Syracuse. In addition to serving as chair of the Health Research Science Board, Dr. DiFino is chair of the Board's Committee on Program Needs and Effectiveness.

Dr. DiFino has served the Board since April 1997.

# **BEVERLY CANIN**

Beverly Canin is a two-time breast cancer survivor. She is past President of Breast Cancer Options, Inc., a survivor-driven, community-based breast cancer support, education and advocacy organization in the Mid-Hudson Valley. She is a graduate of the National Breast Cancer Coalition's (NBCC) Project Leadership, Education and Advocacy Development, or LEAD. She participates annually in the NBCC's Advocacy Training Conference and Lobby Day in Washington, D.C. Ms. Canin is the alternate representative from Breast Cancer Options, Inc. to the Board of Directors of the New York State Breast Cancer Network, and the New York State Breast Cancer Support and Education Network, where she has chaired the Procedures Committee and is a member of the Access to Care Committee.

Ms. Canin has served as a consumer reviewer for the U.S. Department of Defense Breast Cancer Research Program since 2001 at both the peer-review and the programmatic review levels. She also has worked as an advocate reviewer for the California Breast Cancer Research Program. She is a member of Breast Cancer Action and of the Mid-Hudson Valley affiliate chapter of Sisters' Network, Inc.

Ms. Canin is retired, after having worked many years in non-profit administration, including as a consultant for program development and evaluation.

Ms. Canin began serving the Board in July 2008.

# DOUGLAS CONKLIN, PhD

Douglas Conklin, PhD, is Associate Professor of Biomedical Sciences at the SUNY at Albany School of Public Health, Gen\*NY\*Sis Center for Excellence in Cancer Genomics. He received a PhD in Cellular and Molecular Biology at the University of Wisconsin at Madison in 1993 and in 1997 completed a postdoctoral training fellowship on Cancer Genetics at Cold Spring Harbor Laboratory.

His laboratory studies the functional genomics of cellular proliferation in human cells. Specifically, they are looking at the relationship between cellular fat metabolism and breast cancer, are studying redox regulation of cell cycle progression. The group has identified several genes that are required for the survival of breast cancer cells that were previously unknown to play roles in cancer.

Dr. Conklin began serving the Board in February 2012.

#### JAMES B. HICKS

James Hicks, PhD is Research Professor of Cancer Genetics and Molecular Biology at Cold Spring Harbor Laboratory. Dr. Hicks is best known for his work on yeast genetics and moveable DNA elements in the 1980's, and more recently for his work on genomic profiling in breast cancer.

He earned a PhD in 1975 from the University of Oregon, followed by a postdoctoral fellowship at Cornell University where, with Dr. Gerald Fink, he co-developed DNA transformation in yeast. In 1978, he founded the yeast molecular genetics group at Cold Spring Harbor Laboratory. With Cold Spring Harbor Laboratory coworkers Jeff Strathern and Amar Klar, he worked out the molecular details of mating type switching in yeast. Dr. Hicks then spent five years as Director of the PPG Industries Joint Research Group at Scripps Clinic in La Jolla, CA. In 1990, he became one of the founding scientists of ICOS Corporation in Seattle, WA.

Since then he has been a serial entrepreneur and investor in the internet and health sciences until returning to Cold Spring Harbor Laboratory in 2004, where he began his current work collaborating with Dr. Mike Wigler on the genomics and epigenomics of breast cancer. In this work, he and his colleagues are applying next-generation DNA sequencing strategies to identify diagnostic and prognostic markers in breast, ovarian and cervical cancer. Dr. Hicks has published over 100 articles on yeast genetics and cancer genomics.

Dr. Hicks currently serves on the Board of Directors of Barrett Business Services, Inc. and is a co-founder and Director of Virogenomics, Inc. of Portland, OR and GenDx, Inc.

of Roslyn Heights, NY. He is also a scientific advisor to several early stage biotechnology companies.

Dr. Hicks was appointed to the Board in July 2012.

# RUSSELL HILF, PhD

Dr. Hilf is professor of biochemistry and oncology at the University of Rochester School of Medicine and Dentistry. He earned a BS in chemistry from the City College of New York in 1952, and an MS and PhD in biochemistry from Rutgers University. After serving in the U.S. Army and briefly at the Q.M. Food & Container Institute, he held the position of head of cancer endocrinology at the Squibb Institute for Medical Research for 11 years, prior to joining the faculty at the University of Rochester School of Medicine and Dentistry in 1969.

Dr. Hilf's primary research interests lie in the field of hormone action, with emphasis on estrogen and anti-estrogen mechanisms, and on insulin and IGF-1, as they pertain to breast cancer. A second area of research deals with photodynamic therapy of neoplasms. Dr. Hilf has published more than 200 peer-reviewed papers in professional journals and written 40 invited book chapters. He is a member of the American Association for Cancer Research, American Society for Biochemistry and Molecular Biology, The Endocrine Society, and the American Society for Photobiology. He has served as associate editor at Cancer Research for 20 years, and has been on the advisory board of Biochemical Pharmacology and the editorial boards of Oncology Research and Cancer Biochemistry Biophysics. He was elected a fellow by American Association for the Advancement of Science in 1966, received the University of Rochester Alumni Award for Graduate Education in 1992, was a Wellcome Visiting Professor in 1994, and was presented with the Davey Memorial Cancer Research Award by the University of Rochester Cancer Center in 1998.

Dr. Hilf has been a member of: the National Cancer Institute (NCI) Breast Cancer Task Force; the Veterans' Administration Merit Review Board on Oncology; the NCI Cancer Education Committee; and the American Cancer Society's Biochemistry and Chemical Carcinogenesis Committee as chair of its Biochemistry and Endocrinology Committee. He has served three cycles on the U.S. Army Breast Cancer Review Program and two terms on the National Institutes of Health (NIH) Reproductive Endocrinology Study Section, the last two years as chairman. He has completed two terms on the External Scientific Advisory Board for the University of Wisconsin Comprehensive Cancer Center. He also is a member of a scientific review panel for The American Institute for Cancer Research, and a reviewer of grant applications for the New Jersey Cancer Commission.

Dr. Hilf has served the Board since April 1997.

# DIANA E. LAKE, MD

Dr. Lake is a medical oncologist with a practice that is devoted solely to the care of breast cancer patients. Her research interests involve all areas of breast cancer but focus mainly on the development of new therapies, prevention of cancer recurrence

following surgery, and treatment of recurrent disease. Working in conjunction with her colleagues on the Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center and as the liaison in breast medicine to Cancer and Leukemia Group B, a national clinical trial cooperative research group sponsored by the NCI, she is involved in clinical trials to develop better hormonal therapies and improved approaches to treatment before surgery. In addition, she is a member of the NIH Scientific Review Committee, and previously served on the NIH Cooperative Group Review and its Cancer Education committees.

Dr. Lake was appointed to the Board in September 2009.

# DEXTER A. MCKENZIE, MD

Dr. McKenzie earned a medical degree from Meharry Medical College, Nashville, Tennessee, and holds undergraduate degrees in pharmaceutical sciences and chemistry. He completed residency training in combined internal medicine-pediatrics at Kings County Hospital and the SUNY Health Science Center, Brooklyn.

Dr. McKenzie is assistant professor of medicine at SUNY Downstate Medical Center, and teaches medical students and medical residents while conducting original research. His public health interests are further expressed in collaborations with New York City Department of Health and Mental Hygiene initiatives in community participatory research, influenza vaccination and chronic disease abatement.

Dr. McKenzie has provided direct care —in both patient diagnosis and management — of numerous forms of childhood and adult illnesses for more than two decades in both private and hospital-based medical practices. He also serves on several scientific and philanthropic boards.

Dr. McKenzie began serving the Board in June 2010 and concluded his service in June 2012.

# GARY R. MORROW, PhD, MS

Dr. Morrow is professor of radiation oncology and professor of psychiatry at the University of Rochester School of Medicine and Dentistry. He also serves as an Associate Director for Cancer Control at the James P. Wilmot Cancer Center, University of Rochester. He holds undergraduate degrees in mechanical engineering and in English from the University of Notre Dame. Following college, he served in the U.S. Navy Nuclear Power Program for four years and completed patrols on the U.S.S. James K. Polk. He received a MS in psychology and a PhD in clinical psychology from the University of Rhode Island, prior to joining the University of Rochester, where he completed an internship in clinical psychology and a two-year postdoctoral training fellowship in psychosomatic medicine. He also has earned an MS in medical statistics from the University of Rochester.

Since 1982, Dr. Morrow has authored more than 200 peer-reviewed publications in cancer control and been awarded continuous funding for his research in supportive

cancer care and management of cancer and cancer treatment-related side effects. At present, he directs a research base for the NCI's Community Clinical Oncology Program that serves 25 affiliated collaborating institutions throughout the country and has referred more than 600 patients per year to Phase III cancer control clinical trials. His ongoing research is toward the better understanding and management of cancer-induced nausea and cancer-related fatigue.

Dr. Morrow has chaired more than two dozen permanent and *ad hoc* grant-funded review committees for the American Cancer Society, NIH, NCI and the U.S. Department of Defense. He has served on the American Cancer Society Executive Council, as well as the Advisory Council to the National Institute of Nursing Research.

Dr. Morrow began serving the Board in December 2008.

# ARUN PURANIK, MD

Dr. Puranik is director of Image Guided Radiation Therapy in Latham, NY. He obtained a BS degree from Holkar Science College, Indore, India; and an MBBS and a medical degree in radiotherapy from M.G.M. Medical College, also in Indore. Dr. Puranik's postgraduate training included an internship in general medicine at M.R. Hospital, followed by appointment as resident and clinical demonstrator at the Department of Radiotherapy, M.G.M. Medical College. He served as a consultant radiation therapist at the N.P. Cancer Institute, Rajkot, India; and at Nanavati Hospital and Medical Research Center, Bombay, India.

Dr. Puranik completed a residency in the Department of Radiology, Radiation Oncology Division, SUNY Upstate Medical Center, Syracuse, NY, for which he was awarded a Fellowship in Radiation Oncology from the American Cancer Society. He was also a fellow in the Department of Radiation Oncology, Albany Regional Radiation Oncology Program, at Albany Medical College, where he was later named as assistant professor. Prior to his current venture, he was co-chair of the first prostate brachytherapy program in Upstate New York at Samaritan Hospital Cancer Treatment Center, Troy, New York. Dr. Puranik is board-certified in radiation oncology, and in 1997 received the Physician of the Year Award from the Capital District Chapter of the American Cancer Society.

Dr. Puranik has served the Board since July 1998.

# ROBERT RITER

Robert Riter's involvement with the breast cancer community began in 1996 when he was diagnosed with the disease at the age of 40. Unlike many men with breast cancer, Mr. Riter decided to go public about his diagnosis and did so by writing an essay about his experiences that appeared in the July 17, 1997 issue of Newsweek magazine.

Mr. Riter is the Executive Director of the Cancer Resource Center of the Finger Lakes (formerly known as the Ithaca Breast Cancer Alliance). In addition, he writes a regular column about living with cancer for the Ithaca Journal. Those columns were recently

compiled into a book, "The Elephant in the Room: Practical Advice When the Diagnosis is Cancer."

At the national level, Mr. Riter has served on scientific review panels at the U.S. Department of Defense Breast Cancer Research Program and the Susan G. Komen Breast Cancer Research Program. He has participated in Project LEAD and Project LEAD Quality Care training, sponsored by the NBCC, as well as the San Antonio Breast Cancer Symposium.

Prior to his work in cancer education and advocacy, Mr. Riter received an MHSA in hospital administration from the School of Public Health at the University of Michigan, and worked as a health care administrator before teaching health policy and health administration at Ithaca College.

Mr. Riter began serving the Board in July 2008, and became a voting member in August 2010.

# NEETA SHAH, MD

Neeta M. Shah, MD is a board certified internist. She received her medical education at J.N. Medical College, Belgaum, India and completed her residency at Flushing Hospital Medical Center in New York. She is an Assistant Professor of Medicine, Hofstra North Shore-LIJ School of Medicine and Adjunct Clinical Associate Professor of Medicine, New York College of Osteopathic Medicine, and was Clinical Instructor in Medicine, Weill Cornell Medical College.

Dr. Shah is a fellow of the American College of Physicians (ACP) and member of the Health and Public Policy Committee, NY State Chapter of ACP. She is a member of the American Medical Association and the American Medical Women's Association (AMWA), where she has devoted time in mentoring female medical students, and was the first female president of the New York State Program Directors in Internal Medicine. Dr. Shah has received the Physician Mentor Recognition Award from the American Medical Association Women's Physician Congress and numerous awards from several business and advocate entities.

Dr. Shah served most recently as Vice President for Community Services for The Katz Institute for Women's Health at the North Shore-Long Island Jewish Health System, where she worked to build partnerships with communities to provide relevant health information, services and research opportunities. She is a frequent local and national lecturer to health professionals and lay public on various women's health issues, healthy lifestyles and complementary medicine. She has appeared on several television and radio shows and is a regular contributor of health articles to the Healthy Living Digest. Her work has also been featured in Newsday and many other media. She created and hosted a series of video episodes called "What Women Want and Need to Know" under the banner of The Katz Institute for Women's Health.

Dr. Shah was instrumental in launching an annual Women's Health Week and Women's Checkup Day for Suffolk County, New York, which coincides with the National Women's

Health Week initiated by the US Department of Health and Human Services Office on Women's Health.

Her vision to reach a unique audience gave rise to the Health Information Team (HIT) at Citi Field Stadium (NY) in 2010. Through this unique partnership between a health organization and a major league baseball stadium, a permanent location was created where fans can obtain health and wellness information.

Dr. Shah began serving the Board in December 2008.

# ELINOR J. SPRING-MILLS, PhD

Dr. Spring-Mills is a SUNY Distinguished Teaching Professor, and professor of cell and developmental biology and of urology at SUNY Upstate Medical University, Syracuse, NY. She holds a BA degree in physiology from Vassar College, an MA in physiology from Mount Holyoke College, and a PhD in medical sciences (anatomy, biochemistry and pathology) from Harvard Medical School. She completed a postdoctoral fellowship at the NIH Division of Arthritis, Metabolic and Digestive Diseases, and then moved to San Francisco, where for seven years she was assistant chief of cell biology at the Veterans' Administration Hospital; and assistant and, subsequently, associate professor of anatomy at the University of California at San Francisco Medical School.

She has served as a member and chairperson of the Breast Cancer Working Group/Breast Cancer Task Force of the NCI; a founding member of the first Pan American Congress of Andrology; a member of the Educational Policies Committee, American Association of Anatomists; and interim chair of the Department of Anatomy at Upstate Medical School. In addition to publishing research papers and abstracts, she has co-edited three books on the accessory glands of the male reproductive tract and human prostatic cancer. Dr. Spring-Mills is chair of the Board's Committee on Funding and Outreach.

Dr. Spring-Mills has served the Board since May 2006.

#### MARC WILKENFELD, MD

Dr. Wilkenfeld is a board-certified occupational/environmental physician and is Chief of the Division of Occupational and Environmental Medicine at Winthrop University Hospital in Mineola, NY. Previously, he was assistant professor in clinical medicine at Columbia University Medical Center, where he also served as occupational medicine consultant to Columbia's Department of Environmental Health and Safety. He has lectured and trained internal medicine and family practice physicians on aspects of occupational/environmental medicine. Dr. Wilkenfeld also is an attending physician at New York Presbyterian Hospital and Beth Israel Medical Center. He has served as an occupational medicine consultant to corporations, government agencies and other organizations in the U.S. and Europe. He is past-president of the New York Occupational Medicine Association, and has lectured extensively in the field of occupational and environmental medicine.

Following the attacks of September 11, 2001, Dr. Wilkenfeld was named consultant to a number of government agencies, corporations and community groups on the environmental health impact of the disaster. In this role, he reviewed pre- and post-cleanup data and addressed questions regarding the potential health effects of contamination with World Trade Center dust. He moderated and participated in community forums designed to answer the health questions of residents and site workers. He also has evaluated cases of illness related to the disaster. Dr. Wilkenfeld serves as medical advisor to New York City Councilmember Alan Gerson, whose district includes Lower Manhattan. In this role, he continues to assist the Lower Manhattan Community with questions related to the health impacts of September 11.

Dr. Wilkenfeld has served the Board since September 2004.

# Non-voting Members

#### M. SUZANNE HICKS

M. Suzanne Hicks is a nine-year melanoma survivor and a seven-year breast cancer survivor. Ms. Hicks holds a BS in English education from the University of Tulsa, and an MSW degree from the SUNY at Albany. She is a clinical assistant professor of psychiatry at Albany Medical College and closed a 30-year psychotherapy practice in Albany, NY in 2005. Locally, she is a member of CRAAB!, a community-based education and advocacy group. At the national level, she is very active in the NBCC, where she has participated in the NBCC Fund's Project LEAD, and was a speaker at the NBCC Annual Advocacy Conference in 2008. Ms. Hicks was appointed as a member of the Scientific Advisory Committee for the Dr. Susan Love/Avon Foundation Army of Women in 2008.

Ms. Hicks started a local breast cancer peer study group, and spends much of her time as a breast cancer advocate and as an artist with a studio in Albany, NY.

Ms. Hicks began serving the Board in July 2008.

#### **Ex-officio Members**

#### VICTORIA DERBYSHIRE, PhD

Dr. Victoria Derbyshire is the Assistant Director of Wadsworth Center, New York State Department of Health. She joined the Center in 1992 after completing postdoctoral studies at Yale University, where she received her doctorate in molecular biophysics and biochemistry in 1990. As a research affiliate and then research scientist in the Division of Genetic Disorders, Dr. Derbyshire pursued National Institutes of Health-supported studies of introns and inteins, genetic elements that interrupt coding sequences. She holds a patent, along with others, on the use of inteins to purify proteins.

In addition to her research activities, Dr. Derbyshire spearheaded a review of validation data for laboratory developed molecular assays for infectious diseases, and

standardized their submission guidelines for review by the Clinical Laboratory Evaluation Program.

With her appointment in 2006 as Wadsworth's assistant director, Dr. Derbyshire assumed responsibility for issues with broad impact on the Center's public health mission.

Dr. Derbyshire is a breast cancer survivor and was appointed as the DOH Commissioner's designee to the Board in December 2010.

# ANTHONY G. HAY, PhD

Dr. Hay is director of the Institute for Comparative and Environmental Toxicology (ICET), a center for toxicological research, education and outreach located at Cornell University. Dr. Hay is also Associate Professor in the Department of Microbiology at Cornell. He earned a PhD in Soil Microbiology at the University of California, Riverside in 1997. Work in his lab focuses on the ability of microorganisms to degrade xenobiotics. Dr. Hay's research interests include molecular biology, biochemistry, and the ecology of pollutant degradation.

# **EUGENE J. LEFF**

Eugene Leff is a Deputy Commissioner of the New York State Department of Environmental Conservation. He supervises three Divisions: Environmental Remediation, Materials Management and Mineral Resources. Before joining DEC in 2011, he spent many years in the Office of the Attorney General, serving in the Environmental Protection Bureau under six different Attorneys General. He was the Acting Chief of that Bureau's New York City Office and its Deputy Bureau Chief before that. He was lead counsel for the State in the Love Canal Litigation, the Greenpoint (Brooklyn) Oil Pollution Litigation and a recent challenge to the State Superfund Program cleanup goal, as well as in the preparation of a Hudson River PCBs Natural Resource Damages Case. He also represented the Attorney General's Office on Governor Pataki's State Superfund Working Group. He is a graduate of Yale Law School, Yale Graduate School and Columbia College.

Mr. Leff began serving the Board in 2011.

#### MARGARET O'NEIL

Maggie O'Neil is Chief of the Reporting and Certification Section in the Bureau of Pest Management, New York State Department of Environmental Conservation (DEC). The Bureau of Pest Management performs activities related to the Pesticide Reporting Law (PRL) (Environmental Conservation Law Article 33, Title 12). This law requires certified commercial pesticide applicators, technicians, aquatic anti-fouling paint applicators and commercial permittees (including importers, manufacturers and compounders) to submit annual reports detailing pesticide application activities for the prior calendar year. The Bureau of Pest Management is responsible for compliance assistance, public outreach

activities and enforcement of the requirements in the PRL. They manage the data collection requirements of this law and submit a compilation of this information to the Governor annually in the "Annual Report on New York State Pesticide Sales and Applications."

With a background in Business Administration, Maggie began working for DEC in the Division of Operations in 1980. She has also worked in other DEC programs, including the Office of Natural Resources and the Hazardous Waste Management Program. In 1996, the year the PRL was enacted, Maggie began working in the Bureau of Pest Management, and in 2004, became Section Chief of the Reporting and Certification Section.

Ms. O'Neil has reported pesticide activities to the Board since 2005, and has been the DEC Commissioner's designee alternate since 2007.

# APPENDIX VIII COMMENTS FROM PUBLIC HEARINGS PUBLIC COMMENTS OFFERED DURING BOARD MEETINGS

# Comments from Public Hearings

During the public hearings, interested parties may make statements on the Board's operations, the Breast Cancer Research and Education Fund, the Prostate and Testicular Cancer Research and Education Fund, and pesticide reporting.

# 2011

There was no Public Hearing during 2011.

# 2012

# October 19, 2012 Public Hearing

During the October 19, 2012 Public Hearing, Margaret Roberts of CRAAB! commented that using technology such as videoconferencing for Board meetings could help alleviate meeting quorum issues, provided that in-person meetings aren't required.

# Public Comments Made During Board Meetings

In addition to public hearings, a segment of each Board meeting is set aside for public comment. Comments made during 2011-2012 Board meetings are presented below:

# June 22, 2012

Catherine Putkowski-O'Brien thanked the Board for allowing her to observe the meeting.

# APPENDIX IX DEC REPORT ON THE BASIS, EFFICIENCY AND SCIENTIFIC UTILITY OF PESTICIDE REPORTING

# Efficiency and Utility of Pesticide Reporting in 2011 A Report to the Health Research Science Board

Presented by Margaret O'Neil, Chief, Pesticide Reporting and Certification Section New York State Department of Environmental Conservation (DEC) October 19, 2012

Reminder notices were mailed December 15, 2011 to 17,309 applicators, technicians and aquatic anti-fouling paint applicators, and 307 commercial permittees that were required to submit an annual report for report year 2011.

Overdue notices were mailed May 30, 2012 to 2,339 applicators and technicians and 24 commercial permittees notifying them we had not received an annual report from them. The notice gave them until June 15 to submit a report without penalty.

Notices of Violation and Consent Orders were mailed on August 15, 2012 to 1,345 applicators, technicians and aquatic anti-fouling paint applicators, and 11 commercial permittees that still had not submitted a report by June 15<sup>th</sup>.

To date, of the 1,345 applicators, technicians and aquatic anti-fouling paint applicators with violations: 1,017 are still in violation; 11 were deceased; 17 retired in 2011 and then did not file a report; 176 voluntarily surrendered their certification; 30 paid the penalty; 94 reports were amended to either include the name and certification number of someone that had been left off the original report, or to correct ID numbers that were listed incorrectly on the report.

Of the 11 commercial permittees with violations: 6 are still in violation; 2 paid the penalty; 1 violation was removed because the company had retired their commercial permit; 1 voluntarily surrendered the commercial permit; and 1 had a typo on the report and listed the number incorrectly.

The total number of records (which includes sales and applications) reported for report year 2011 was 7,052,750. Of those, 5,901,599 were submitted electronically and 1,151,151 were submitted on paper reports.

Funding for the Pesticide Reporting Law program has been cut over the years. DEC used to receive \$2,025,000 for the program in years 2005/2006, 2006/2007 and 2007/2008. In 2008/2009, we received \$0. In 2009/2010 the Governor proposed \$575,000 in his budget, but DEC only received \$500,000. In 2010/2011, DEC received \$575,000. In 2011/2012, we received \$960,000.

This is not enough money to fund the program. Our contracts alone amounted to approximately \$1.4 million each year for database maintenance, groundwater

monitoring, data keypunching and electronic report administration. Therefore, DEC has had to cut funding to all contracts.

DEC had to cut funding to Cornell University for the database maintenance. For fiscal year 2010/2011, we cut their contract amount from \$698,000 to \$300,000. Therefore, the staff at Cornell working on the Pesticide Sales and Use Database project were cut from eight to two full-time and one half-time employee. Their staffing and budget amount has remained at that level since that time.

DEC Pesticide Reporting Law staff was originally 10 people in the Central Office. With budget and staffing cuts, layoffs and retirements, we are unable to backfill positions. Now we have two people, and only one is working on the Pesticide Reporting Law program. The Pesticide Reporting Section was merged with the Certification Section in 2004 and I spend a majority of my time working on other issues within the section.

At the current level of funding, the program will not be able to process the data currently collected. The program is looking closely at cost saving measures, including limited the data that are required to be reported, and posting only the pesticide data on the website, rather than full annual reports.

When we had ten staff, we reviewed the data as it came in and when errors were identified, we contacted the person submitting the report and worked with them to correct the data before it was submitted to be keypunched. We can no longer review the data as it comes in. We open the reports, box them up and ship them for data entry. Cornell developed a program that reviews the data and identifies errors within specific parameters and provides those error reports to DEC. As time and staffing allows, we reach out to the person that submitted the report and work with them to correct the data. We then provide the corrected data to Cornell to revise the database.

We have not released annual report data since the 2005 report year. We identified gross errors that affected the data statewide for 2006, 2007 and 2008 report years. We worked with the company to fix the errors and resubmit the data. We have found additional errors several times since that point each time we review the data. We have made multiple revisions to the data in an attempt to provide the best quality data possible. There are still many errors in the data. However, we do not have the staff or resources to continue to review and revise the data. We are falling farther and farther behind. I have asked permission to release the data on the website without the accompanying report to the Governor and Legislature since we do not have staff to work on the report.

The total spent on the Pesticide Reporting Law program since its inception (1996/1997) is over \$42 million. Only 2 entities have requested the confidential data. New York City DOHMH requested the confidential data to be used for a surveillance project on birth outcomes in New York City; and Cornell University's Water Resources Institute (one of DEC's contractors for groundwater monitoring) requested the confidential data to help them decide where to put monitoring wells. The confidential data elements are the addresses, and dates of application.

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#### **APPENDIX X**

#### RESEARCH ACCOMPLISHMENTS

**Margaret Roberts**, CRAAB!, "True Burden of Breast Cancer Risk Factors" Education and Demonstration Project, 10/1/10-9/30/12, \$149,942.

This project was undertaken to create presentation software (MS PowerPoint) lectures and related materials to educate a generation of students and the wider community on factors related to breast cancer risk, including exposure to environmental pollutants. Lectures feature up-to-date knowledge and evidence-based medicine, with each version shaped for particular audiences, from medical, nursing and college students to the concerned public. The objective is to educate about primary prevention of cancer and to promote healthier behaviors and environments aimed at reducing risk of new and recurrent breast cancer.

Collaborations with scientists, medical professionals, writers, advocates, and educators have strengthened the dialogue among science researchers, medical professionals and community health educators, and is expected to help each with a deeper understanding of current environmental health and genetics research, evidence-based medicine, and how to present information for different audiences in clear and concise ways that address the complexity of the issues.

Two versions of a lecture on risk factors for breast cancer were created. One version was presented to college students and the other version to members of community organizations who also received a supplemental brochure to review and evaluate. The lectures were presented to 480 students at six colleges, and to 67 members of four community organizations who completed pre- and post-lecture surveys. The survey data were analyzed and the analysis showed that the lectures and brochure were highly effective, but also showed areas that needed improvement. With this analysis, and input from a physician, a cancer center community outreach nurse, professors and project staff, the lectures were refined and a single MS PowerPoint lecture was developed.

The lecture is now available for use as an educational tool for students and the general public. It has been shared with New York State Breast Cancer Network organizations and will be posted on the CRAAB! website: <a href="http://craab.org/">http://craab.org/</a>. This material will also be posted for public dissemination via HRSB's website: <a href="http://www.wadsworth.org/extramural/breastcancer/">http://www.wadsworth.org/extramural/breastcancer/</a>.

The project team plans to organize a regional conference to debut the final version of the lecture, present the study results, and have cancer researchers speak on various topics covered in the presentation.

**Andrei Bakin, PhD**, Roswell Park Cancer Institute, "Targeting Integrin Signaling in Breast Cancer Progression," 10/01/10 – 9/30/13, \$360,000.

The researchers are studying integrin- $\beta$ 5 to determine if integrin- $\beta$ 5 and associated proteins are potential risk factors in breast cancer.

Breast cancer metastases are linked to epithelial-mesenchymal transition, or EMT, and a cell invasive capacity. In the EMT process, cells break their contacts with neighboring cells, acquiring the ability to migrate and invade surrounding tissues and blood vessels. TGF- $\beta$  cytokines are potent inducers of EMT and invasion. Therapeutic targeting of TGF- $\beta$  is challenging due to tumor-suppressor activity of TGF- $\beta$  in early-stage cancers. The investigators discovered that integrin- $\beta$ 5 is required for the TGF- $\beta$ -induced EMT and that integrin- $\beta$ 5 has a novel activity during EMT, mediating the formation of specific cell-matrix adhesions. These adhesions are likely to mediate the EMT process.

Further, investigators determined that integrin- $\beta$ 5 is important for the invasive capacity of breast carcinoma cells. Integrin- $\beta$ 5 is critical for tumor cell growth in anchorage-independent conditions, a property that closely correlates with the metastatic potential. The orthotopic mouse studies showed that suppression of integrin- $\beta$ 5 markedly reduced tumor initiation and growth, whereas re-expression of integrin- $\beta$ 5 restores the tumorigenicity of cells. Histological studies revealed deficiencies in tumor angiogenesis and vascular endothelial growth factor, or VEGF production.

The researchers identified a specific region of integrin- $\beta$ 5 that is responsible for adhesion and biochemical events linked to EMT, invasion and cell proliferation. Next, Integrin- $\beta$ 5 mutants will be tested in EMT, invasion and anchorage-independent assays and integrin- $\beta$ 5-related markers in BrCa-tissue microarrays will be assessed.

This work may lead to the rapeutics inhibiting the pro-oncogenic activities of TGF- $\beta$  and Integrin- $\beta$ 5 and associated proteins may serve as biomarkers of breast cancer progression/metastasis.

**Alice Ceacareanu, PhD**, State University of New York at Buffalo, "Modulation of Inflammatory Response by Diabetes Management in Breast Cancer Patients: A Potential Modifier of Breast Cancer Prognosis?" 10/01/10 – 9/30/12, \$348,988.

Survival following breast cancer is poorer in women with type 2 diabetes (T2DM), and this could be attributed to the actual diabetes pharmacotherapy. Higher cancer-related mortality reported in insulin users suggests that insulin or drugs stimulating insulin production may trigger an environment that nurtures tumor growth. Additionally, there are well established correlations between T2DM, insulin resistance and chronic inflammation. Management of T2DM with oral drugs that do not increase insulin production might be an effective strategy for improving overall disease prognosis within this group of breast cancer survivors.

Medical and pharmacotherapy information was retrieved for all newly diagnosed breast cancer cases between 1997 and 2007 (n=3485). The researchers identified 290 eligible patients with diabetes at the time of breast cancer diagnosis. This list was cross-linked with a list of existing specimens in a bio-bank and corresponding bio-specimens for 98 of

the patients were successfully identified. Additionally, 196 control-matched breast cancer non-diabetes mellitus cases were selected for comparison. A specific biomarker-capture analysis was performed to evaluate a total of 37 plasma biomarkers in 294 patient samples.

The researchers learned that diabetic patients who were treated with oral drugs that do not increase insulin production were more likely to survive longer and experience less recurrence, and that insulin treatment for diabetes management is associated with worst breast cancer prognosis.

Additional prospective studies are needed to confirm this hypothesis and reproduce these findings. Findings consistent with this hypothesis will have direct and immediate applicability in breast cancer care. Screening and clinical intervention can be easily implemented for improved patient outcomes.

**Kluger Yuval, PhD**, NYU School of Medicine, "A Quantitative Immunofluorescence-Based approach to the Classification of Intermediate Recurrence Risk Early Stage Breast Cancer Patients," 10/01/10 - 9/30/13, \$339,336.

Advances in chemotherapy have resulted in increased survival for early stage breast cancer. However, not all patients need chemotherapy; the majority of patients are cured with surgery, radiation and anti-hormonal therapy. Tests using tumor-based biomarkers have recently been incorporated into clinical care, geared towards identifying patients who do not need chemotherapy.

The most commonly used test is called oncotype DXTM, which is highly useful, but is technically complicated, and cannot be done in routine pathology laboratories. It divides patients into "low", "intermediate" and "high" risk groups for developing metastatic disease. Typically the low risk group does not get chemotherapy, whereas the high risk does. The benefit that the intermediate group (over 40%) receives from this test is questionable. If the intermediate group patients could be reclassified to low or high risk using additional biomarkers, it would eliminate the need for chemotherapy for thousands of patients who don't need it, while selectively administering chemotherapy to those whose disease is more likely to recur.

Investigators hypothesize that a similar assay, using different technology that is easier to apply in routine laboratories, can provide equal prognostic ability and that a modified test incorporating additional biomarkers will enable them to reassign patients in the intermediate group to high and low risk categories.

A new method of quantitative immunofluorescence is being used. AQUA biomarker technology has been developed by collaborators at Yale University to study tumors from three cohorts of patients treated at Yale and NYU. Six hundred samples are being analyzed for 14 protein markers and results will be compared to those available from the commercial oncotype test.

The investigator has setup a state-of-the-art computer server and has further improved the algorithms both in terms of model assessment, stability analysis and efficiency.

**Mark Robson, PhD**, Sloan-Kettering Institute for Cancer Research, "Optimal Timing of Genetic Testing for Women with Newly Diagnosed Breast Cancer," 10/01/10 – 9/30/13, \$314,971.

Women with mutations are at increased risk for later developing a second primary cancer in the opposite breast, and for ovarian cancer. *BRCA* gene mutation testing is now an accepted part of the medical management of women with breast cancer, and breast surgeons frequently offer *BRCA* mutation testing to women with newly diagnosed breast cancer. Options for management of these risks include increased screening (including breast screening with MRI) or preventive surgery. If the mutation screen is positive, these women often choose to undergo bilateral mastectomy, even if they would otherwise be candidates for breast conservation. The investigators hypothesized that women who are experiencing high levels of distress about their diagnosis are more likely to defer genetic testing. They further hypothesized that there will a subset of women who choose pre-surgical testing and later regret the decision.

The investigators are offering women who have been newly diagnosed with breast cancer, and who have a significant risk of carrying a *BRCA* mutation, the option of either *immediate BRCA* testing, receiving results before the completion of local surgical treatment (pre-surgical), or *delayed* testing after the completion of surgical treatment (post-surgical). This study is designed to: assess participants' general and cancerspecific distress, attentional style, choice preference and decisional conflict with respect to genetic testing; observe their choices about testing and prophylactic surgery; and determine their level of regret with respect to those decisions at six and 12 month time points.

To date, 39 subjects have been recruited, 37 of who chose immediate testing and two who declined testing indefinitely. Although only three patients were found to have mutations, 13 chose to undergo bilateral mastectomy. Baseline data have been collected and are being summarized, although there are insufficient numbers for the original comparison of immediate versus delayed testing. The second aim is to assess satisfaction and regret with respect to timing of genetic testing.

Recruitment has been hampered by a number of factors, including a greater than expected proportion of individuals who meet eligibility criteria but who have already been tested by others before they came to Sloan-Kettering Institute for Cancer Research for their initial consultation. Modifications to eligibility criteria and study procedures are being considered to enhance recruitment.

The results of this research will help determine the safety of offering women genetic testing for BRCA mutations at the time of their initial breast cancer diagnosis. It will also provide invaluable guidance to clinicians as to which patients are at greatest risk for regret with respect to the decisions about testing and preventive surgery.

**Herbert Samuels, PhD**, NYU School of Medicine, "Targeting a Novel Pathway That Selectively Modulates Apoptosis of Breast Cancer Cells," 10/01/10 – 9/30/12, \$360,000.

Investigators have identified a novel pathway which can specifically lead to the death of breast cancer cells. Previously, they identified the factor NRIF3, a protein which, when

expressed in breast cancer cells, rapidly kills the cells through a process referred to as programmed cell death or apoptosis. The region of NRIF3 that is responsible for cell killing is a short 30 amino acid sequence, called "Death Domain-1" or DD1.

Recently the researchers also identified a protein DD1-Interacting Factor-1 (DIF-1) in breast cancer cells that binds DD1. Findings thus far suggest that DIF-1 selectively represses one or more genes in breast cancer cells that lead to cell death when they are expressed. Studies also demonstrate the feasibility of selectively inducing cytotoxicity, suggesting that breast cancer cells contain a novel "death switch" involving the DIF-1 pathway that can be specifically triggered by NRIF3 or DD1.

Investigators also identified FASTKD2 as the gene that is regulated by DIF-1 that leads to breast cancer cell death. They have developed conditions to further identify breast cancer specific components of the DIF-1 complex and to express and purify the FASTKD2 kinase domain to identify the cellular phosphorylation targets of FASTKD2.

The researchers are continuing studies to understand the function and protein components of DIF-1. These studies could lead to the development of novel and more selective therapeutics against breast cancer.

**Jose Silva, PhD**, Columbia University, "Functional Genomics Studies To Uncover Novel Anticancer Therapies," 10/01/10 – 9/30/12, \$360,000.

Cancer therapy is transitioning from classical chemotherapy to patient-oriented strategies. Novel therapies based on the specific molecular changes that drive tumorigenesis in every patient are emerging as less toxic and more efficient alternatives to classical treatments.

In order to identify targets for personalized anticancer strategies, the researchers proposed the use of genetic synthetic lethal interactions. These occur when two genetic alterations that are individually innocuous appear in the same cell, causing growth inhibition. This concept can be exploited to identify gene functions that, when blocked, reduce exclusively the viability of tumor cells that carry a preexisting genetic lesion.

Thus, they have envisioned using genome-wide ribonucleic acid interference (RNAi) screens to identify genes that, when silenced, exclusively reduce the viability of tumor cells carrying specific genetic lesions without affecting normal ones. RNAi genetic screens with four major breast cancer genetic alterations (PI3K, Cyclin-D1, PTEN and RB) are under studied. In this project, we dissected *in vitro* and validated *in vivo* the functional profile of these four genetics.

Importantly, we found that several kinases with available small molecule inhibitors score at the top of the list for PTEN and PI3K mutants. Among them were AURKB and PLK. Importantly, the use of the specific small molecule inhibitors BI 2536 and Hesperidin recapitulated the lethal phenotype. Initial characterization of the mechanism of lethality revealed that inhibition of PLK and AURKB in PTEN and PI3K mutant lines induced mitotic failure that invariably leads to apoptosis.

Our finding set the foundation for further studies targeting these kinases as "individualized therapy" in patients with alterations in PTEN and PI3K genes. This is especially relevant for patients with triple-negative tumors which present a high percentage of PTEN alterations and for which targeted therapies are not currently available.

**Ping Tang, PhD**, University of Rochester, "Predicting Bone Metastasis of Breast Cancer," 10/01/10 – 9/30/13, \$360,000.

Up to 80% of advanced breast cancer patients will develop bone metastases, the most common systematic failure in breast cancer patients. It indicates the disease has entered an incurable stage and impacts patients' quality of life significantly.

The investigators hypothesize that certain breast cancers that will develop bone metastasis have a unique molecular makeup compared to those that will not develop bone metastasis. Further, they believe that the unique molecular makeup can be detected by immunohistochemical (IHC) analysis.

Currently most studies use either single IHC marker analysis, which is not powerful enough for accurate prediction, or multigene analysis that requires costly and complicated technology on fresh/frozen tissue, which usually is not available clinically. A more accurate prediction of the subgroup of patients with high risk for bone metastasis would result in more focused surveillance, effective prophylaxis, and early treatment to improve survival and quality of life in this subgroup of breast cancer patients. This project uses formalin-fixed paraffin-embedded tissue, which is readily available in most laboratories, to study the IHC expression pattern(s) of a limited number of key molecules in a systematic fashion in order to identify a predictive pattern(s) that will be readily applicable for clinical application.

Investigators: 1) have identified 152 breast cancer cases with bone metastasis, 136 with lymph node metastasis, 113 with visceral organ metastasis, and 161 without any type of metastasis; 2) are comparing their differential expression patterns of key molecules in breast carcinogenesis and bone metastasis; and 3) are seeking to identify any patterns that predict high risk for bone metastasis by routine immunohistochemical (IHC) analysis. For each case, key clinical and pathological data have been recorded, and microscopically reviewed to confirm pathological diagnosis.

The researchers are constructing tissue microarrays (TMA); each microarray contains 100-120 pinpoints of tissue, and allows the examination and comparison of many cases at one time. Forty to 50 microarrays will be constructed.

Next, sections will be cut, mounted on glass slides, and stained with selected immunocytochemical markers (antibodies). Each stain produces a different pattern, and the researchers are examining these in order to determine if there are one or more patterns that appear with regularity for different tumor types.

Success in identifying a unique immunocytochemical expression pattern that is predictive for bone metastasis will enable more focused surveillance, effective prophylaxis, and early treatment in this subgroup of breast cancer patients.

#### **APPENDIX XI**

#### PUBLICATIONS AND MEETING ABSTRACTS RESULTING FROM BOARD AWARDS

Awardees continue to make important contributions to breast cancer scientific and education research. During the 2011-2012 reporting period, awardees reported the following new publications and meeting abstracts in the field as a result of funding from the HRSB:

C026587 Roswell Park Cancer Institute

Project Title: Targeting Integrin Signaling in Breast Cancer Progression

Gervasi M, Bianchi-Smiraglia A, Cummings M, Zheng Q, Wang D, Liu S and **Bakin AV**. "JunB Contributes to Id2 Repression and the Epithelial–Mesenchymal Transition in Response to Transforming Growth Factor–β." *Journal of Cell Biology*. 2012; 196(5):589-603.

# C026588 SUNY at Buffalo

Project Title: Modulation of Inflammatory Response by Diabetes Management in

Breast Cancer Patients: a Potential Modifier of Breast Cancer Prognosis?

**Ceacareanu AC**, Hong C-C, Jackowiak CM, Zhang Y, Khoury T, Nimako GK, Ekonomidis D, Wintrob ZAP, Kossoff E, Kublas TM and Forrest A. "Use of Insulin Sensitizers is Associate with Better Hormone-Receptor Pattern and Improved Breast Cancer Outcomes." Meeting abstract presented at the 103<sup>rd</sup> Annual Meeting of the American Association of Cancer Research, March 31 - April 4, 2012; Chicago, IL

**Ceacareanu AC**, Hong C, Brennan III JJ, Epstein M, Kossoff E, Nimako GK, Patel K, Wintrob ZAP and Forrest A. "Statins Treatment Use in Diabetics With Breast Cancer: a Potential C-Reactive Protein Mediated Benefit." Meeting abstract presented at the Breast Cancer Symposium of the American Society of Clinical Oncology, September 8 -10, 2011; San Francisco, California.

Shah AB, Jackowiack CM, Ekonomidis D, Hong C-C and **Ceacareanu AC**. "Cholesterol Drugs Improve Disease Free Survival in Type 2 Diabetics With Breast Cancer". Meeting abstract presented at 45th ASHP Midyear Clinical Meeting, December 5 - 9, 2010; Anaheim, California.

Fu HW, Wintrob ZAP, Martens CJ, Hong C-C and **Ceacareanu AC**. "Could Cholesterol Drugs Modulate Inflammation in Type 2 Diabetics With Breast Cancer?" Meeting abstract presented at 45th ASHP Midyear Clinical Meeting, December 5 - 9, 2010; Anaheim, California.

C026590 NYU School of Medicine

Project Title: A Quantitative Immunofluorescence Based Approach to Classification of

Intermediate Recurrence Risk Early Stage Breast Cancer Patients

Strino F, Parisi F, Kluger Y. "VDA, a Method of Choosing a Better Algorithm with Fewer Validations." *PloS One.* 2011; 6(10):e26074.

C026592 NYU School of Medicine

Project Title: Dissection of a Novel Pathway that Selectively Mediates Apoptosis of

**Breast Cancer Cells** 

Yeung, K. T., S. Das, J. Zhang, A. Lomniczi, S. R. Ojeda, C-F Xu, T. A. Neubert, and H. H. Samuels. "A Novel Transcription Complex That Selectively Modulates Apoptosis of Breast Cancer Cells Through Regulation of FASTKD2."

Mol Cell Biol. 2011; 31:2287-2298.

# **APPENDIX XII**

# STATUS OF AGENCY ACTIONS ON HRSB RECOMMENDATIONS ON PESTICIDE REPORTING

2011-2012

SOURCE*	RECOMMENDATION	STATUS
	Recommendations not requiring a change in legislation	
2000 (2)	1. Continue to inform researchers of the availability of funds for research on cancer and of the availability of the pesticide data for research.	This is an ongoing effort. The availability of funds continues to be publicized. A web page describing and linking to the Pesticide Sales and Use Database (Pesticide Registry, or PSUR) is being added to DOH's Environmental Public Health Tracking web site.
2000 (3), 2006 (2), 2010 (5)	2. DEC should emphasize accurate reporting of the data by continuing to develop and implement quality assurance and quality control procedures.  Incorporate checks on the following (2006):  a. very similar amounts reported for multiple ZIP codes  b. liquids reported as pounds and solids as gallons  c. quantities reported at county and ZIP code levels that differ by more than an order of magnitude  d. outliers	This is an ongoing effort that involves staff from both DEC and Cornell University. They refined the quality control program and Department staff does a brief review of reports to ensure basic criteria were met. These criteria were established to maximize the volume of data that can be transferred to the master database. In 2006, at the request of DEC, new computer programs were developed by Cornell to review the data using the criteria developed and previously used by DEC in a manual review of the reports. These changes were necessary due to funding and staffing cuts. Error reports are produced, and outreach efforts are conducted to correct the data. If errors are too numerous, the report is rejected and returned to the business or applicator to be corrected and resubmitted. Once the corrections are made, the data are posted to the website.
2000 (4c)	3. Explore ways to assist the pest control industry with the difficulty of reporting amount of concentrate when commercial applicators deal with diluted material.	This is an ongoing educational effort. DEC has done extensive telephone outreach on a case-by-case basis educating applicators how to report correctly. In addition, the Department and Cornell have developed programs to conduct quality checks on reports containing quantities that appear to fall outside of accepted parameters. Staff review reports containing these "out of range" quantities and the responsible applicators and businesses are contacted.

SOURCE*	RECOMMENDATION	STATUS
		With the approval of the applicator or business, staff corrects the reporting errors. Once the corrections are made, the data are posted to the website.
2000 (4d)	4. Explore ways to assist reporting of locations without street address (e.g., rights of way, streams, parks, and aerial applications), such as use of a Geographic Information System (GIS) approach.	This is an ongoing effort. A GIS approach cannot currently be used for reporting in all areas of the state; some options, such as reporting mile markers, stream tributary numbers, etc., have been implemented, while others are still being explored.
2000 (4e)	5. Explore methods to increase or improve reporting, possibly through development of additional outreach and/or enforcement activities and electronic reporting.	An electronic reporting option is in place and was emphasized at workshops held throughout the state and by direct mailing to all applicators and sellers. Due to extensive outreach efforts conducted by DEC on a case-by-case basis, we receive more than half of the PRL data in an electronic format. However, to mandate electronic reporting would require a change in law by the Legislature. Enforcement actions are taken each year against applicators and sellers that do not report.
2006 (3), 2010 (3)	6. Explore the possibility of making available an application line-item dataset with no confidential information for counties and ZIP codes.	DEC will explore the feasibility of a line-item dataset for counties and ZIP codes. There is no funding or staff available at this time to pursue this.
2006 (4), 2010 (4)	7. To county and ZIP code data, explore the possibility of adding number of applications, license type to distinguish structural and landscaping activities, and summary statistics (mean, median, maximum)	DEC will explore the feasibility of adding the number of applications to county and ZIP code data. In most cases, reports are not submitted by an individual applicator, but by businesses, listing all applicators in their employ. In addition, many applicators have multiple categories of certification. Therefore, license type cannot be determined for each application. There is no funding or staff available at this time to pursue this.
2006 (5), 2010 (8)	8. Explore ways to include fields from the Pesticide Product Ingredient and Manufacturer System (PIMS) or to include the ability to link to PIMS or to the EPA Pesticide Product Information System.	There are links to PIMS available on the website, but not within the report data. This will require major programming changes to the database. There is no funding or staff available at this time to pursue this.

SOURCE*	RECOMMENDATION	STATUS
2006 (7)	9. Increase NYSDEC's budget and the funds provided by contract to Cornell.	
2010 (1)	10. Release publicly available data for 2006 and subsequent years	During quality reviews, there were numerous major errors identified in the data for 2006, 2007 and 2008. The Department worked with the entities that were responsible for the errors to correct the data. The revised data was entered into the database. As staffing resources allow, the Department is working on releasing the data for 2006, 2007 and 2008.
	Recommendations that may require a change in legislation	
2006 (1), 2010 (2)	Allow local health agencies access to the confidential data for surveillance purposes	Researchers including local health agencies can apply to the Health Research Science Board for access to the confidential data. One of the criteria for releasing the data is that the data have to be used for human health related research. Some forms of surveillance may be considered research, while other forms may not meet the criterion for human health related research. A change in law by the Legislature would be required to allow local health agencies access to the confidential data without requesting the data from the Health Research Science Board.
	Recommendations requiring a change in legislation	
2000 (L1)	1. Change the date by which DEC must issue its report to the Governor and Legislature to allow a longer period for quality control and quality assurance of the data. If partial data are released, they should be available as soon as possible; the final report should contain only high quality data; and the data and report should be readily accessible.	Change of date requires change by Legislature. Quality assurance of the data and education efforts to regulated community are ongoing efforts. All non-confidential data are publicly available on the internet or by requesting a CD-ROM.

SOURCE*	RECOMMENDATION	STATUS
2000 (L2)	2. DEC should identify options for including data on pesticides applied by private applicators (primarily farmers) in the database and report on these options to the Board.	Including these data in database and reports requires a change in the law by the Legislature.
2000 (L3), 2006 (L2), 2006 (L3), 2010 (7)	3a. DEC should identify options for including data on target organism and crops to which pesticides are applied in the database and report on these options to the Board.  3b. Mandate reporting of dosage rate and target organism.  3c. Include crop/site of application (for those reporting) and include the crop/site for private applicator sales of general use pesticides intended for agricultural purposes.	Including these data in database and reports requires a change in the law by the Legislature.
2000 (L4)	4. DEC should identify options for including data on pesticides purchased and applied by private citizens in the database and report on these options to the Board, and should review the upcoming reports from Wisconsin and Oregon, which are currently conducting scoping studies of this issue.	The Board reviewed results of Oregon's pilot survey on household use reporting and voted that the information from Oregon did not support including household pesticide use data in New York's reporting requirements at this time.
2006 (L1), 2010 (6)	5. Mandate electronic reporting	An electronic reporting option is in place and was emphasized at workshops held throughout the state and by direct mailing to all applicators and sellers. Due to extensive outreach efforts conducted by DEC on a case-by-case basis, we receive more than half of the PRL data in an electronic format. However, to mandate electronic reporting would require a change in law by the Legislature.
2006 (L4)	6. Revise the requirement for the length of time that commercial applicators, sellers of pesticides, and private applicators must maintain records, to a period of not less than 7 years.	This would require a change in law by the Legislature. The law currently states that records must be maintained for a period not less than 3 years.

SOURCE*	RECOMMENDATION	STATUS
	Recommendations that have been implemented	
2000 (4a)	Include a reference in the report to the Governor and Legislature to the Pesticide Poisoning Registry Report from DOH.	Done. The annual report to the Governor and Legislature now includes a reference to the Pesticide Poisoning Registry.
2000 (4b)	2. Include a reference in the report to the Governor and Legislature to documents that will provide information on the potential for specific pesticides to leach into the groundwater.	Done. The annual report to the Governor and Legislature includes a reference to documents that provide information on the potential for specific pesticides to leach into the groundwater.
2002-03 (3)	3. Include in the biennial reports references to studies that have been stimulated or influenced by the database as examples of how PSUR data could stimulate higher-level research.	A list of studies published in the scientific literature that were stimulated or influenced by the PSUR data appeared in the 2003-04 biennial report. The list is being updated in each subsequent report.
2000 (1), 2006 (1)	DEC should express data in both pounds of product and pounds of active ingredient	Done. This requires knowing the specific gravity of every product registered in NYS. DEC altered its internal processes to capture this information as products are registered. It has taken several years to capture most of the specific gravities for the 14,000 registered products. DEC made significant progress toward expressing data in both pounds of product and pounds of active ingredient. DEC and Cornell developed a website which provides active ingredient summarizations of the data, starting with year 2003 data.
2002-03 (2)	5. Modify the web sites for ease of use and flexibility in creating reports.	The active ingredient website provides a more modern look and feel. It provides multi-year searching capabilities. It also incorporates a number of features that enhance the site's usability. For example, to make it easier to identify which ZIP codes to use in a search, the user can select all the zip codes that are contained in or partially contained in a county. Documents have been added to the site to assist in pesticide product searches, including FAQs, a data dictionary, and glossary.

SOURCE*	RECOMMENDATION	STATUS
2002-03 (4)	6. Explore the possibility of using pesticide-poisoning data in conjunction with the PSUR data.	Using pesticide poisoning data in conjunction with the PSUR data would not be productive since about 99% of the pesticide poisoning reports involve improper use of unrestricted pesticides that can be purchased at retail outlets, such as hardware stores and home centers. These products are not included in the PSUR database. However, DOH is exploring the usefulness of the PSUR data for environmental health surveillance as part of the Environmental Public Health Tracking Program.
2006 (6)	7. Explore ways to decrease the time from a researcher's request for the confidential data to receipt of the data.	The Pesticide Committee modified its process to improve efficiency by incorporating a pre-review process whereby 3 members of the committee review the application to determine if it has enough information for the committee to make an informed decision. Without delaying scheduling of a meeting, staff members work with the applicant to obtain any additional information needed before the meeting.
2002-03 (1)	8. Explore whether the data can be aggregated by different categories such as use category, different geographical units, etc.	Done. The active ingredient website contains data aggregated by use category (fungicides, insecticides, herbicides, etc.), as well as statewide, county, ZIP code or DEC Region.

<sup>\*</sup>Year of survey from which recommendation originated, with number from the original table or list.

#### APPENDIX XIII

# REPORTS AND JOURNAL ARTICLES FROM RESEARCH STUDIES USING OR REFERRING TO THE PESTICIDE SALES AND USE DATABASE

# Studies Using the Pesticide Sales and Use Database

Steenhuis T, Richards B, Walter MT, Sinkevich M, Garcia, S, Liu B, Pacenka, S, Porter K, Porter MJ, Barber A, Reidy P and Burnell W. "Surveying Upstate NY Well Water for Pesticide Contamination – Year 1 Final Report to the New York State Department of Environmental Conservation (Task 6A-AMOU157)." July 2006.

Steenhuis T, Richards B, Walter MT, Toevs I, Salvucci A, Pacenka S, Porter K, Porter MJ, Tsoi S and Mosher D. "Surveying Upstate NY Well Water for Pesticide Contamination – Year 2 Final Report to the New York State Department of Environmental Conservation." October 2009.

Horton MK, Jacobson JB, McKelvey W, Holmes D, Fincher B, Quantano A, Diaz BP, Shabbazz F, Shepard P, Rundle A and Whyatt RM. "Characterization of Residential Pest Control Products Used in Inner City Communities in New York City." *J Expo Sci Environ Epidemiol.* 2011; 21:291-301.

Richards BK, Pacenka S, Salvucci AE, Saia SM, Whitbeck LF, Furdyna PM and Steenhuis TS. "Surveying Upstate NY Well Water for Pesticide Contamination: Cayuga and Orange Counties." *Groundwater Monitor Remed.* 2012; 32:73-82.

#### Studies Referring to the Pesticide Sales and Use Database

Whyatt RM, Camann DE, Kinney PL, Reyes A, Ramirez J, Dietrich J, Diaz K, Holmes D and Perera FP. "Residential Pesticide Use During Pregnancy Among a Cohort of Urban Minority Women." *Environ Health Perspect.* 2002; 110:507-514.

Berkowitz GS, Obel J, Deych E, Lapinski R, Godbold J, Liu Z, Landrigan PJ and Wolff MS. "Exposure to Indoor Pesticides During Pregnancy in a Multiethnic, Urban Cohort." *Environ Health Perspect.* 2003; 111:79-84.

Brenner BL, Markowitz S, Rivera M, Romero H, Weeks M, Sanchez E, Deych E, Garg A, Godbold J, Wolff MS, Landrigan PJ and Berkowitz G. "Integrated Pest Management in an Urban Community: a Successful Partnership for Prevention." *Environ Health Perspect.* 2003; 111:1649-1653.

Perera FP, Rauh V, Tsai WY, Kinney P, Camann D, Barr D, Bernert T, Garfinkel R, Tu YH, Diaz D, Dietrich J and Whyatt RM. "Effects of Transplacental Exposure to Environmental Pollutants on Birth Outcomes in a Multiethnic Population." *Environ Health Perspect.* 2003; 111:201-205.

Whyatt RM, Barr DB, Camann DE, Kinney PL, Barr JR, Andrews HF, Hoepner LA, Garfinkel R, Hazi Y, Reyes A, Ramirez J, Cosme Y and Perera, FP. "Contemporary-Use Pesticides in Personal Air Samples During Pregnancy and Blood Samples at Delivery Among Urban Minority Mothers and Newborns." *Environ Health Perspect.* 2003; 111(5):749-756.

Berkowitz GS, Wetmur JG, Birman-Deych E, Obel J, Lapinski RH, Godbold JH, Holzman IR and Wolff MS. "In Utero Pesticide Exposure, Maternal Paraoxonase Activity, and Head Circumference." *Environ Health Perspect.* 2004; 112:388-391.

Kass DE, Thier AL, Leighton J, Cone JE and Jeffery NL. "Developing a Comprehensive Pesticide Health Effects Tracking System for an Urban Setting: New York City's Approach." Environ Health Perspect. 2004; 112:1419-1423.

Whyatt RM, Rauh V, Barr D, Camann D, Andrews HF, Garfinkel R, Hoepner L, Diaz D, Dietrich J, Reyes A, Tang D, Kinney PL and Perera FP. "Prenatal Insecticide Exposures and Birth Weight and Length Among an Urban Minority Cohort." *Environ Health Perspect.* 2004; 112:1125-1132.

Perera FP, Rauh V, Whyatt RM, Tang D, Tsai WY, Bernert JT, Tu YH, Andrews H, Barr DB, Camann DE, Diaz D, Dietrich J, Reyes A and Kinney PL. "A Summary of Recent Findings on Birth Outcomes and Developmental Effects of Prenatal ETS, PAH, and Pesticide Exposures." *Neurotoxicology.* 2005; 26:573-87.

Whyatt RM, Camann D, Perera FP, Rauh VA, Tang D, Kinney PL, Garfinkel R, Andrews H, Hoepner L and Barr DB. "Biomarkers in Assessing Residential Insecticide Exposures During Pregnancy and Effects on Fetal Growth." *Toxicol. Appl. Pharmacol.* 2005; 206:246-54.

Rauh VA, Garfinkel R, Perera FP, Andrews HF, Hoepner L, Barr DB, Whitehead R, Tang D and Whyatt RW. "Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First 3 years of Life Among Inner-City Children." *Pediatrics.* 2006; 118:e1845-e1859.

Williams MK, Rundle A, Holmes D, Reyes M, Hoepner LA, Barr DB, Camann DE, Perera FP, Whyatt RM. "Changes in Pest Infestation Levels, Self-Reported Pesticide Use, and Permethrin Exposure During Pregnancy After the 2000-2001 U.S. Environmental Protection Agency Restriction of Organophosphates." *Environ Health Perspect.* 2008; 116:1681-1688.

Whyatt RM, Garfinkel R, Hoepner LA, Andrews H, Holmes D, Williams MK, Reyes A, Diaz D, Perera FP, Camann DE, Barr DB. "A Biomarker Validation Study of Prenatal Chlorpyrifos Exposure Within an Inner-City Cohort During Pregnancy." *Environ Health Perspect.* 2009; 117:559-566.

# **ABBREVIATION KEY**

CRAAB! Capital Region Action Against Breast Cancer!

DEC New York State Department of Environmental Conservation

DOH New York State Department of Health

ECL Environmental Conservation Law

HRSB Health Research Science Board

LEAD Project Leadership, Education and Advocacy Development of the NBCC

NBCC National Breast Cancer Coalition

NCI National Cancer Institute

NIH National Institutes of Health

NYU New York University

PCBs Polychlorinated biphenyls

PHL New York State Public Health Law

PI Principal Investigator

PRL Pesticide Reporting Law (Environmental Conservation Law, Article 33, Title 12)

PSUR Pesticide Sales and Use Reporting

RFA Request for Applications

SUNY State University of New York

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