

BIOGRAPHICAL SKETCH

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NAME Michael A. Carducci, M.D.	POSITION TITLE Associate Professor of Oncology and Urology		
eRA COMMONS USER NAME mcarduc1			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Georgetown University, Washington, D.C.	A.B.	1983	American Studies
Wayne State University, Detroit, MI	M.D.	1988	Medicine
University of Colorado HSC, Denver, CO	Intern/Resident	1988-91	Medicine
University of Colorado HSC, Denver, CO	Chief Resident	1991-92	Medicine
Johns Hopkins University SOM, Baltimore, MD	Research Fellow	1992-95	Oncology

A. Positions and Honors.**Professional Experience:**

1995-96 Instructor of Oncology and Urology, Johns Hopkins University School of Medicine
 1996-2001 Assistant Professor of Oncology and Urology, Johns Hopkins University
 2001- Associate Professor of Oncology and Urology, Johns Hopkins University
 2003- Chair, Prostate Cancer Subcommittee, Eastern Cooperative Oncology Group
 2004- Co-Leader, Prostate Cancer Program, Kimmel Cancer Center at Johns Hopkins
 2006- Co-Leader, Chemical Therapeutics Program, Kimmel Cancer Center at Johns Hopkins

Honors:

1986 Alpha Omega Alpha
 1988 M.D. with High Distinction, Wayne State University

B. Publications (selected from 141 peer-reviewed publications):

- Bubley GJ, Carducci MA, Dahut W, Dawson N, Daliani D, Eisenberger M, Figg WD, Freidlin B, Halabi S, Hudes G, Hussain M, Kaplan R, Myers C, Oh W, Petrylak DP, Reed E, Roth B, Sartor O, Scher H, Simons J, Sinibaldi V, Small EJ, Smith MR, Trump DL, Vollmer R, Wilding G. Eligibility and response guidelines for phase II clinical trials in androgen independent prostate cancer: recommendations from the PSA working group. *Journal of Clinical Oncology*, 17:1-7, 1999.
- Pili R, Kruszewski MP, Hager B, Lantz J, Carducci MA. Combination of phenylbutyrate and 13-cis-retinoic acid inhibits prostate tumor growth and angiogenesis. *Cancer Res* 61: 1477 – 1485, 2001.
- Carducci MA, Gilbert J, Bowling MK, Eisenberger MA, Sinibaldi V, Noe D, Chen TL, Grochow LB, Donehower RC. A phase I clinical and pharmacologic evaluation of sodium phenylbutyrate on a 120 hours infusion schedule. *Clin Cancer Res* 7: 3047-3055, 2001.
- Gilbert J, Baker SD, Bowling MK, Grochow L, Figg WD, Zabelina Y, Donehower RC, Carducci MA. A phase I dose escalation trial to maximally tolerated dose of oral sodium phenylbutyrate in patients with refractory solid tumor malignancies. *Clin Cancer Res* 7: 2292 - 2300, 2001.
- Carducci MA, Bowling MK, Rogers T, Eisenberger M, Sinibaldi V, Donehower R, Leahy T, Moyse D, Carr R, Isaacson J, Janus TJ, Padley RJ, Nelson JB. Atrasentan, an endothelin receptor antagonist for refractory adenocarcinomas: Phase I and pharmacologic evaluation. *J Clin Oncol*, 20: 2171-2180, 2002.
- Carducci MA, Padley RJ, Breul J, Vogelzang NJ, Zonnenberg BA, Daliani DD, Schulman CC, Nabulsi AA, Humerickhouse RA, Weinberg MA, Schmitt JL, Nelson JB. The effect of endothelin-A receptor blockade with atrasentan on tumor progression in men with hormone refractory prostate cancer: A randomized, placebo-controlled trial. *J Clin Oncol* 21:679-689, 2003.

Principal Investigator/Program Director (Last, First, Middle): Carducci, Michael A.

7. Nelson JB, Nabulsi AA, Vogelzang NNJ, Breul J, Zonnenberg BA, Daliani DD, Schulman CC, Carducci MA. Suppression of prostate cancer-induced bone remodeling by the endothelin receptor A antagonist, atrasentan. *J Urology* 169:1143-1149, 2003.
8. Scher HI, Eisenberger M, D'Amico AV, Halabi S, Small EJ, Morris M, Kattan MW, Roach M, Kantoff P, Pienta KJ, Carducci MA, Agus D, Slovin SF, Heller G, Kelly WK, Lange PH, Petrylak D, Berg W, Higano C, Wilding G, Moul JW, Partin AW, Logothetis C, Soule H. Eligibility and outcomes reporting guidelines for clinical trials for patients in the state of a rising prostate-specific antigen: recommendations from the prostate-specific antigen working group. *J Clin Oncol* 22:537-556, 2004.
9. Shabbeer S, Carducci MA. Targeting deacetylation for therapeutic benefit. *IDrugs* 8:144-154, 2005.
10. Carducci MA. What is more exciting? The activity of docetaxel in early prostate cancer or the successful collaboration between urologists and medical oncologists to complete a study in early prostate cancer? *J Clin Oncol*, 23:3304-3307, 2005.
11. Rudek MA, Zhao M, He P, Hartke C, Gilbert J, Gore SD, Carducci MA, Baker SD. Pharmacokinetics of 5-azacytidine given with phenylbutyrate in patients with refractory solid tumors or hematologic malignancies. *J Clin Oncol*, 23: 3906-3911, 2005
12. Sausville EA, Carducci MA. Making bad cells go good: The promise of epigenetic therapy. *J Clin Oncol*, 23: 3875-3876, 2005.
13. Basaria S, Muller D, Carducci M, Egan J, Dobs AS. Hyperglycemia and insulin resistance in men with prostate cancer undergoing androgen deprivation therapy. *Cancer*, 106:581-588, 2006.
14. Messersmith WA, Baker SD, Lassiter L, Sullivan RA, Dinh K, Almuete VI, Wright JJ, Donehower RC, Carducci MA, Armstrong DK. Phase I trial of bortezomib (PS-341) in combination with docetaxel in patients with advanced solid tumors. *Clin Cancer Res* 12:1270-1275, 2006.
15. Braga-Basaria M, Muller DC, Carducci MA, Egan J, Dobs AS, Basaria S. Lipoprotein profile in men with prostate cancer undergoing androgen deprivation therapy. *Intl J Impot Res*, April 13, 2006. (Epub ahead of print)
16. Small EJ, Carducci MA, Burke JM, Rodriguez R, Fong L, van Ummerson L, Yu DC, Aimi J, Ando D, Working P, Kim D, Wilding G. A Phase I trial of intravenous CG7870, a replication-selective PSA-targeted oncolytic adenovirus, for the treatment of hormone-refractory, metastatic prostate cancer. *MolTher* 14:107-117, 2006.
17. Green LJ, Marder P, Ray C, Cook CA, Jaken S, Herbst R, Carducci M, Britten C, Basche M, Eckhardt G, Thornton D. Development and validation of a drug activity biomarker that demonstrates target inhibition in cancer patients receiving enzastaurin, a novel phospho-kinase C- β inhibitor. *Clin Cancer Res*, 12: 3408-3415, 2006.
18. Simons JW, Carducci MA, Mikhak B, Lim M, Biedrzycki B, Borellini F, Cliff Sm, Hege KM, Ando DG, Piantadosi S, Mulligan R, Nelson WG. Phase I/II trial of an allogeneic cellular immunotherapy in hormone-naïve prostate cancer. *Clin Cancer Res*, 12: 3394-3401, 2006.
19. Gore SD, Baylin S, Sugar E, Carraway H, Miller CB, Carducci M, Grever M, Galm O, Dausen T, Karp JE, Rudek MA, Zhao M, Smith BD, Manning J, Jiemjit A, Dover G, Mays A, Zweibel J, Murgo A, Weng L-J, Herman J. Combined DNA methyltransferase and histone deacetylation inhibition in the treatment of myeloid neoplasms. *Cancer Res* 66: 6361-6369, 2006.
20. Xia Q, Chowdhury W, Chen C-L, Carducci M, Rodriguez R. Chronic administration of valproic acid inhibits prostate cancer cell growth in vitro. *Cancer Res* 66:7237-7244, 2006.
21. Carducci MA, Musib L, Kies M, Pili R, Truong M, Brahmer JR, Cole P, Sullivan R, Riddle J, Stewart J, Enas N, Sinha V, Thornton DE, Herbst RS. Dose escalation and pharmacokinetics of enzastaurin (LY317615), an oral PKC β inhibitor, in patients with advanced cancer: a Phase I study. *J Clin Oncol*. 2006; 24: 4092-4099.
22. Thompson IM, Carroll PR, Carducci MA. Recommendations for defining and treating high risk localized prostate cancer. *J Urology*. 2006; 176: S6-S10.
23. Braga-Basaria M, Muller DC, Carducci MA, Egan J, John M, Dobs AS, Basaria S. Metabolic syndrome in men with prostate cancer undergoing long-term androgen deprivation therapy. *J Clin Oncol*. 2006; 24: 3979-3983.
24. Qian DZ, Kachhap SK, Collis SJ, Verheul HMW, Carducci MA, Atadja P, Pili R. Class II histone deacetylases are associated with VHL independent regulation on HIF-1 α . *Cancer Res*. 2006; 66: 8814-8821.

C. Research Support

Ongoing

5P30CA006973-44 (Abeloff)

05/01/06-04/30/11

NIH/NCI

Regional Oncology Research Center

This project funds the CORE Grant for the Johns Hopkins Oncology Center. Specific effort involves directing the scientific and operational aspects of the Analytical Pharmacology Core which includes pharmacological trial design, sample handling, analytical method development, validation, and implementation, data interpretation and Pharmacokinetic and Pharmacodynamic modeling.

Role: Co-Investigator

UO-1 CA70095 (Carducci)

03/01/03 - 02/28/08

NIH/NCI

"Phase I Clinical Trials of Anticancer Agents"

The main goal of this project is to evaluate new agents for advanced cancer

Role: PI

NO1-CM27018 (Bleumke)

09/01/02-08/31/07

NIH/NCI

Early Clinical Trials of Imaging Agents

The main goal of this project is to evaluate new imaging agents in patients with cancer.

Role: Co-Investigator

R25CA95260 (Myers)

07/01/02– 06/30/07

UC Davis (Carducci)

NIH/NCI

"Simultaneous Care: Linking Palliative Care to Clinical Trials"

The main goal of this project is to evaluate palliative care interventions with cancer patients enrolling on early phase clinical trials.

Role: Principal Investigator at Hopkins

KO7 CA769073 (Dy)

09/27/02-06/30/07

NIH/NCI

Artificial Nutrition in Terminally Ill Cancer Patients

The major goal of this project is to evaluate palliative care interventions with cancer patients receiving artificial nutrition at the end of life.

Role: Mentor

P50-58236 SPORE in Prostate Cancer (Carducci)

08/01/03-03/31/08

NIH/NCI

"Project # 2- Restoration of Gene Function in Prostate Cancer by reversal of CpG Island DNA Methylation and Modulation of Chromatin Structure "

The main goal of this project is conduct pre-clinical in vitro and clinical studies optimizing dose and schedule of inhibitors of DNA methyltransferase and histone deacetylase

Role: Project PI

P50CA103175 (Bhujwalla)

08/01/03-07/31/08

NIH/NCI

"Johns Hopkins University In Vivo Cellular and Molecular Imaging Center"

The main goal of this project is to develop new imaging techniques for advanced cancer.

Role: Co-Investigator

Agensys Clinical Research and Dev. (Carducci)

08/09/05-08/31/07

A Phase I, Open-Label, Multi-Center, Dose Escalation Study of the Safety and Pharmacokinetics of AGS-PSCA Given as Monotherapy in Subjects with Advanced Prostate Cancer

Principal Investigator/Program Director (Last, First, Middle): Carducci, Michael A.

Role: PI

DOD (Carducci) 01/01/06-12/31/08
Prostate Cancer Clinical Trials Group- Johns Hopkins Kimmel Cancer Center Site
The major goal of this project is to discover and develop new prostate cancer treatments.
Role: PI

P50-CA88843 (Davidson) 12/01/06-11/30/11
NIH
SPORE in Breast Cancer
The main goal of this grant is to support a translational breast cancer research program of 4 research projects and 3 cores.
Role: Co-Investigator

CA185002 (Carducci) 07/01/06-06/30/08
Bristol-Myers Squibb
A Phase I Dose –Escalation Study of BMS-641988 in Patients with Castration-Resistant Prostate Cancer
The main goal of this study is to determine a recommended Phase 2 dose of BMS-641988 that may be safely administered to patients with castration-resistant prostate cancer.
Role: PI

ATN224005 (Carducci) 09/01/06-08/31/12
Attenuon, LLC.
A Randomized, Phase II Study Comparing Two Dose Levels of ATN-224 in Patients with Biochemically Relapsed, Hormone-Naïve Prostate Cancer
The main goal of this study is to determine the safety, tolerability, and efficacy of ATN-224 in prostate cancer by comparing two different dose levels.
Role: PI

H6Q-MC-S029 (Carducci) 11/21/06-11/21/07
Eli Lilly & Company
A Phase I Safety Evaluation of Oral Enzastaurin in Combination with Bevicizumab in Patients with Advanced/Metastatic Cancer
The main goal of this study is to evaluate the safety and tolerability of Oral Enzastaurin in combination with Bevicizumab in patients with solid tumors.
Role: PI

Cellgate (Carducci) 07/01/06-06/30/07
A Phase II Study of CGC-11047 in Patients with Metastatic Hormone Refractory Prostate Cancer
The main goal of this study is to evaluate the efficacy of CGC-11047 in prostate cancer.
Role: PI

Merck Research Laboratories (Carducci) 02/01/06-06/30/07
A Phase I Randomized, Multicenter, Double-Blind Study of MK-0429 in the Treatment of Men with Hormone Refractory Prostate Cancer and Metastatic Bone Disease (Protocol No. 011)
The major goal of this study is to evaluate the safety and tolerability of 4 weeks of MK-0429 therapy.

0103-002 (Carducci) 05/21/04-06/30/07
MethylGene, Inc.
Phase I Study of MGCD0103 Given as a Three Time Weekly Oral Dose in Patients with Advanced Solid Tumors or Non-Hodgkin's Lymphoma
The major goal of this project is to determine the safety and tolerability of increasing doses of MGCD0103 when administered to patients with advanced solid malignancies or NHL.