



In this Issue:

Thank You for a Successful 2008 Tax Season.....	1
Michigan Launches Redesigned Website.....	1
Michigan Automated Prescription System (MAPS): Assists Health Professionals with Tracking Patients' Controlled Substance Use.....	2
Register Today for ENACCT's <i>Your Role in Cancer Clinical Trials</i> E-Course Series.....	2
Second Cervical Cancer Vaccine Protects Against Additional HPV Types.....	2
Pain Management Booklet to be Distributed to Michigan Physicians.....	3
FDA Approves Opioid Pain Reliever with Required Risk Reduction Plan.....	3, 5
Breast Cancer Genetic Testing...What's the Difference Anyway?.....	4-5
August Calendar of Events.....	6

Thank You for a Successful 2008 Tax Season

Thank you for your assistance in promoting the two cancer funds added to the 2008 Voluntary Contribution Schedule. We are excited to report that Amanda's Fund for Breast Cancer Prevention raised **\$71,628**. The Prostate Cancer Research Fund collected **\$52,235**.

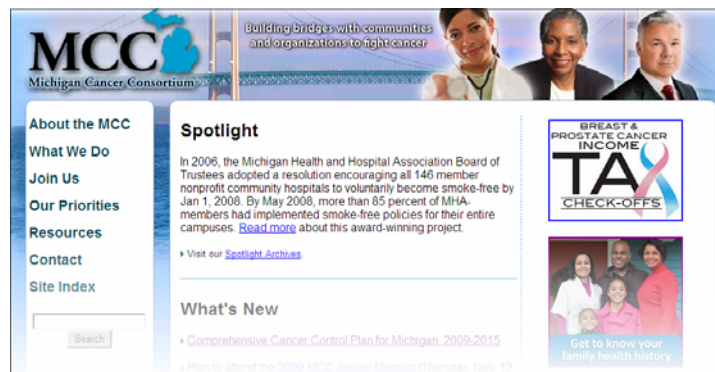
All the money from Amanda's Fund will go directly to the Michigan Breast and Cervical Cancer Control Program, which provides free breast and cervical cancer screening and diagnostic services to low-income women in our state. Dollars raised from the Prostate Cancer Research Fund will be used to support prostate cancer researchers here in Michigan.

While we are extremely grateful for the generous donations made to funds, we need your help now more than ever in promoting the funds to your partners. Both of these funds must raise \$100,000 each during the 2009 tax season to stay on the Voluntary Contributions Schedule. If the funds raise less than \$100,000 each, they will be removed from the Schedule and legislation will need to be reintroduced and passed before they can be added back to the Schedule.

As we prepare to develop our marketing plan for the 2009 tax season, please let us know your thoughts on how we can better publicize the funds. What do you think worked? What should we do differently? Please send all comments and suggestions to cochairs@michigancancer.org. Thank you.

MCC Launches Redesigned Website

The MCC is excited to announce that its website has recently been redesigned at the request of our members. The redesigned site boasts a new look as well as improved navigation. Please take a moment to look at the new site (www.michigancancer.org) and let us know what you think by emailing cochairs@michigancancer.org.



Michigan Automated Prescription System (MAPS): Assists Health Professionals with Tracking Patients' Controlled Substance Use

According to Dr. Scott Fishman, author of the Federation of State Medical Boards' *Responsible Opioid Prescribing: A Physician's Guide*, "Appropriate concerns about the potentially harmful or addictive aspects of opioid medications can be balanced with the equally valid needs of optimal pain relief with adequate risk management." One of the tools that will allow for adequate risk management is the Bureau of Health Professions' Michigan Automated Prescription System (MAPS).

Users of MAPS - dentists, veterinarians, physicians, nurse practitioners, physician assistants, and pharmacists - are encouraged to request MAPS reports on their patients to review their prescription records of Schedule II - V controlled substances. Online requests for reports take, on average, less than five minutes. Faxed requests take a minimum of 24 hours.

Become a MAPS user today! It takes only minutes to register as a user of MAPS. For registration instructions or for more information on MAPS, please visit the Department of Community Health website at www.michigan.gov/healthlicense, or contact MAPS at mapsinfo@michigan.gov or 517-373-1737.

Register Today for ENACCT's Your Role in Cancer Clinical Trials E-Course Series

The Educational Network to Advance Cancer Clinical Trials [ENACCT] has recently developed a series of learning courses to help further advance access and accrual to cancer clinical trials.

"Your Role in Cancer Clinical Trials" is a series of free, one hour e-learning courses which enable cancer clinical trial staff, patient advocates and community leaders, and primary care providers to learn more about promoting and discussing all treatment options, including clinical trials, for every person diagnosed with cancer. Participants will also learn how to promote greater access to and participation in cancer clinical trials, especially for minorities and the medically underserved.

- *Your Role: How You Can Be An Advocate for Cancer Clinical Trials in Your Community*
- *Your Role: Why Cancer Clinical Trials Are Important for My Practice* (CEU Provided)
- *Your Role: Enhancing Your Recruitment and Retention Practices Among Medically Underserved Patients* (CEU Provided)

For more information about these free courses, visit <http://www.enacct.org/our-programs/your-role-cancer-clinical-trials>

Second Cervical Cancer Vaccine Protects Against Additional HPV Types

A large international trial funded by GlaxoSmithKline Biologicals shows that the Cervarix vaccine is highly effective against infections with [human papillomavirus \(HPV\)](#) types 16 and 18. [Final results](#) of the Papilloma Trial Against Cancer In Young Adults (PATRICIA) were published July 8 in *The Lancet*.

The Cervarix vaccine reduced the risk of precancerous lesions known as [grade II cervical intraepithelial neoplasias \(CIN2+\)](#) by nearly 93 percent in participants who completed the full sequence. The vaccine also provided a lesser but significant degree of cross-protection against HPV types 31, 33, and 45. This added protection could raise the potential effectiveness of HPV vaccination from about 70 percent to between 81 and 86 percent.

About 62 percent of women in the trial had never been exposed to any of the 14 HPV types associated with cervical cancer. This group "is closest to the population targeted by universal mass HPV vaccination," said the authors, referring to young girls who are not sexually active. Only one event of CIN2+ was observed in 5,449 of these unexposed study participants.

Cervarix is licensed in 90 countries and was approved recently by the World Health Organization, which allows United Nations agencies and partners to use the vaccine in developing countries. The vaccine is still under review and [awaiting approval](#) by the FDA.

<http://www.cancer.gov/ncicancerbulletin/071409/page3#b>

Pain Management Booklet to be Distributed to Michigan Physicians

This summer the Bureau of Health Professions will be sending licensed Michigan physicians, medical residents, physician assistants, and advance practice nurses whose official address of record is in Michigan, a copy of the Federation of State Medical Boards' (FSMB) booklet, *Responsible Opioid Prescribing: A Physician's Guide*.

This continuing medical education activity (7.25 credits can be earned online) is jointly sponsored by the Alliance of State Pain Initiatives, the Federation of State Medical Boards, and the University of Wisconsin School of Medicine.

This clear, concise handbook has been written for the FSMB by Scott M. Fishman, MD, Chief of the Division of Pain Medicine and Professor of Anesthesiology at the University of California Davis, and Past President of the American Academy of Pain Medicine.

Responsible Opioid Prescribing: A Physician's Guide provides concrete steps that can be taken to reduce risks and improve patient care in those cases where opioid therapy should be considered as part of a patient's treatment plan. The booklet also reflects the basic tenets of the FSMB's 2004 *Model Policy for the Use of Controlled Substances for the Treatment of Pain*.

The Bureau of Health Professions recently established a new Pain Management and Palliative Care Program, the mission of which is to assist both health care professionals and the public in providing and being provided safe, adequate, and appropriate pain and symptom management.

Additional information can be found on the Bureau's Pain & Symptom Management website at www.michigan.gov/pm.

If you have any questions regarding this new program or the distribution of the *Responsible Opioid Prescribing: A Physician's Guide* booklet, please call or email Susan Affholter at 517 373-7303 or affholters@michigan.gov.

FDA Approves Opioid Pain Reliever with Required Risk Reduction Plan

On July 16, 2009, the U.S. Food and Drug Administration approved Onsolis, medication intended for certain patients with cancer to help manage breakthrough pain – severe flares of pain that break through regular pain medication.

Onsolis is in a class of drugs that deliver the potent opioid fentanyl through the mouth's mucous membranes. Onsolis delivers fentanyl via an absorbable film that sticks to the inside of the cheek. The drug is indicated for the management of breakthrough pain in patients with cancer, ages 18 and older, who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medicine. Such patients are considered opioid tolerant because of their current opioid medication use.

Because fentanyl is subject to abuse and misuse, Onsolis was approved with a Risk Evaluation and Mitigation Strategy, or REMS, which is a required plan for managing risks associated with a drug or biological product.

"Onsolis can provide strong pain relief to patients who are opioid tolerant. But for patients who are not opioid tolerant, it can lead to overdose, sudden serious breathing difficulties, and death," said Bob Rappaport, MD, director, Division of Anesthesia, Analgesia and Rheumatology Products in the FDA's Center for Drug Evaluation and Research (CDER). "For this reason, Onsolis should be prescribed only under the safeguards provided by the FDA-required REMS and by health care professionals knowledgeable about Onsolis and the use of potent opioid medications."

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require that drugs and biological products have a REMS to ensure that the benefits of a drug or biological product outweigh its risks.

As part of the REMS, Onsolis will only be available through a restricted distribution program called the FOCUS program. Under this program, only those prescribers, patients, and pharmacies registered with the program will be able to prescribe, dispense, and receive Onsolis. The FOCUS program will provide training and educational materials to prescribers and pharmacy personnel, and a counseling call will be placed to patients prior to dispensing to ensure they have been adequately educated about the appropriate use of the drug. Prescription orders will be filled only by participating pharmacies that send the product directly to the patients' homes.

Onsolis was approved with a boxed warning, which states that the medication should not be used for the management of migraines, dental pain, or postoperative pain or by patients who use opioids intermittently, or on an as-needed basis. It also warns that the drug should be kept out of the reach of children and should not be substituted for other fentanyl products.

~ Continued on Page 5 ~

Breast Cancer Genetic Testing...What's the Difference Anyway?

An Overview of Oncotype DX, *MammaPrint*, H:I Ratio, and BRCA 1/2 Testing

~ Submitted by the Michigan Cancer Genetics Alliance

In an era in which knowledge of genetics and genomics is rapidly expanding, it is increasingly difficult to keep up on the details of genetic or genomic tests; tests that are rapidly made available for use in medicine. One of the most confusing areas for medical practice is sorting out the uses and implications of testing for inherited (germline) genetic changes versus testing for non-inherited or sporadic (somatic) genetic changes.

In general, genetic testing looks for changes (mutations) in our genes, chromosomes, or gene products (proteins). In the case of breast cancer, there are two distinct types of genetic testing. One type looks for inherited mutations in major cancer susceptibility genes such as **BRCA1** and **BRCA2**, most often by testing a blood sample. This testing can provide information about an individual's risk of developing breast or ovarian cancer and the risk to their family members. The second type of breast cancer genetic testing looks for sporadic genetic mutations which are only found in breast tumor cells and are not passed on in families. There are several different "brands" of somatic genetic testing for breast cancer; they are performed on tumor tissue that is removed during a biopsy or surgery and are known as "gene-expression profiling tests." Profiles from these tests can provide information about the future recovery of a person with breast cancer. Examples of gene expression profile tests include **Oncotype DX**, ***MammaPrint***, and **H:I Ratio** testing. Testing for both the inherited genetic mutations and somatic mutations can provide valuable information to patients and physicians, but each type of test has a different purpose and is used in different circumstances.

Gene Expression Profiling to Determine Recurrence Risk

Oncotype DX, *MammaPrint*, and H:I ratio testing are three separate tests that look for changes in many cancer-related genes. These tests are performed on actual tumor tissue since the changes are not present in healthy tissue. Gene mutations found through these tests were not inherited from either parent, but rather occurred sporadically in certain breast cells leading to the development of a cancer. This type of gene testing may help patients and physicians decide on the best possible treatment plan by providing a prediction of the **RECURRENCE** risk; or chance that the original cancer will return. Oncotype DX, *MammaPrint*, and H:I ratio testing provide estimates of the chance that a cancer will recur 5 years or 10 years after the initial diagnosis. Oncotype DX more widely used than the other two tests as it has been available longer than *MammaPrint* or H:I ratio testing. Oncologists and surgeons typically offer and order these tests without involving additional specialists. Oncotype DX is primarily offered to women with estrogen positive tumors, and negative lymph nodes. *MammaPrint* is offered to women with estrogen positive *or* negative tumors, and 3 or less positive lymph nodes. And H:I ratio testing is typically offered to women treated solely with Tamoxifen for whom alternative therapies (i.e., chemotherapy) may be considered and who have estrogen positive tumors with negative lymph nodes.

Results of the above gene expression profiles are reported as a likelihood of recurrence (high, intermediate, or low with Oncotype DX and high or low with *MammaPrint* and H:I ratio testing). Those patients with intermediate or high scores are considered more likely to experience a recurrence, and therefore may have a greater chance of benefitting from chemotherapy. Those with low scores may choose not to have chemotherapy in order to avoid the unpleasant side effects of treatment.

The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group found insufficient evidence to recommend for or against the use of tumor gene expression profiles to improve patient survival outcomes. They found preliminary evidence of potential benefit of Oncotype Dx testing for some women who face decisions about treatment options, i.e., reduced adverse events for low risk women avoiding chemotherapy. However, EGAPP could not rule out the potential for harm for other women, for example, breast cancer recurrence in "low risk women" that might have been prevented with further treatment. The Working Group suggested that clinicians decide on a *case by case* basis by deciding if gene expression profiling adds value beyond current prognostic markers, how to weigh benefits and harms for a particular patient, and if the test was relevant to the patient. The Working Group noted that if profiling is used, counseling, and educational materials should be provided to patient to address potential benefits and harms and how results may affect decisions regarding therapy. To read more, please visit <http://www.egappreviews.org/docs/EGAPPWG-BrCaGEPRec.pdf>.

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Breast Cancer Genetic Testing...What's the Difference Anyway? continued

BRCA1,2 (BRCAAnalysis) to Determine Hereditary Cancer Risk

BRCAAnalysis searches an individual's DNA for mutations in the *BRCA* genes. Individuals who inherit mutations in these genes have substantial increased risks for developing breast and ovarian cancer, often at young ages. In addition, these genes change and their associated cancer risks can be passed on in a family from one generation to the next (50% risk to first degree relatives of a carrier individual). *BRCA* gene testing can help patients and physicians decide on the possible prevention plans by identifying risk for developing these cancers. For example, women with *BRCA* mutations may choose to have their breast tissue or ovaries completely removed as part of their cancer treatment or prior to an initial diagnosis of cancer.

BRCA 1 and *BRCA 2* results can be positive for a mutation, negative for a mutation, or a variant of uncertain significance. Each of these results has different implications for the individual and family. Perhaps the most difficult dilemma is when a family with multiple breast and ovarian cancer diagnoses has a negative (or normal) result. This may leave women and their health care providers wondering what to do next. A genetics specialist can help in this situation by assessing risks and helping with choices about testing for other hereditary cancer syndromes.

In 2005, the United States Preventive Service Task Force (USPSTF) issued a statement (<http://www.ahrq.gov/clinic/uspstf/uspsbrgen.htm>) recommending that women in the general population who have certain specific family history patterns of breast and/or ovarian cancer be referred for genetic counseling and evaluation for BRCA testing. They also recommended against referral and testing for women without the high risk family histories.

The world of genetic and genomics is expanding at a rapid pace and many providers find it difficult to stay apprised of the latest information and testing. For this reason, the specialty of Medical Genetics utilizes the expertise of board certified Geneticists (physicians) and board certified Genetic Counselors (master's level providers) to assist patients and their referring physicians; providing knowledge, testing information, and the service of test coordination and insurance verification are among the responsibilities of this specialty. Please remember that the state of Michigan requires that the providers obtain written informed consent discussing risks, benefits, and limitations prior to any presymptomatic or predictive genetic test. To read more about this important law, please visit www.migeneticsconnection.org/policy.shtml.

Resources:

- USPSTF (2005). Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement. *Annals of Internal Medicine* 143(5): 355-361.
- Nelson et. al (2005). Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Systematic Evidence Review for the U.S. Preventive Services Task Force. *Annals of Medicine* 143(5): 362-379.
- EGAPP <http://www.egapreviews.org/>
- NSGC <http://www.nsgc.org>

FDA Approves Opioid Pain Reliever with Required Reduction continued

In February, the FDA announced that it would require a REMS for a different class of opioids that offer long-acting and extended-release medication. The FDA has held a series of meetings with stakeholders, including a large public meeting, and also solicited written public comments to hear more about how to develop this REMS.

"The REMS for Onsolis was specifically tailored to that drug and should not be viewed as a model REMS for long-acting and extended-release opioid products," said Douglas Throckmorton, MD, deputy director of CDER. "Developing the comprehensive REMS for these other products is a complex undertaking. We will take the time necessary to review all of the public comments and will proceed in a deliberate manner toward the mutual goals of patient access and patient protection."

Onsolis is manufactured by Aveva Drug Delivery Systems, Miramar, FL, and marketed under license from BioDelivery Sciences International Inc. of Raleigh, NC, by Meda Pharmaceuticals Inc., based in Somerset, NJ

For more information see: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm172039.htm>

August

<i>Sun</i>	<i>Mon</i>	<i>Tue</i>	<i>Wed</i>	<i>Thu</i>	<i>Fri</i>	<i>Sat</i>
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
				Argileh-Use Prevention: Challenges and Opportunities <ul style="list-style-type: none"> • 9:00 am – 3:30 pm • Byblos Banquet Center – Dearborn 		
16	17	18	19	20	21	22
				Michigan Advisory Committee on Pain and Symptom Management <ul style="list-style-type: none"> • 9:00 am – 12:00 pm • Ottawa – Lansing 		
23	24	25	26	27	28	29
	NIH State-of-the-Science Conference: Family History and Improving Health <ul style="list-style-type: none"> • http://consensus.nih.gov/2009/2009FamilyHistorySOS031main.htm 	NIH State-of-the-Science Conference: Family History and Improving Health <ul style="list-style-type: none"> • http://consensus.nih.gov/2009/2009FamilyHistorySOS031main.htm 	NIH State-of-the-Science Conference: Family History and Improving Health <ul style="list-style-type: none"> • http://consensus.nih.gov/2009/2009FamilyHistorySOS031main.htm 	Free Tobacco Treatment Webinar: Pharmacotherapy and the Quit Tobacco Process <ul style="list-style-type: none"> • 11:00 am – 12:00 pm • http://education.mha.org/eweb/ 		
			MCC Tobacco Control/Lung Cancer Special Project Web Conference <ul style="list-style-type: none"> • 10:00 am – 11:00 am • http://breeze.mch.train.org/cancersection/ 			
30	31					

2009