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LETTER TO THE EDITOR

"Skin Cancer *Is* Skin Cancer": Readers Counter Editorial, Urge Re-assessment of Classifications

We write in response to the editorial, "Skin Cancer *Is* Skin Cancer," published in the July issue of this Journal.[1] It refutes the recommendations of a National Cancer Institute (NCI) report entitled "Addressing overdiagnosis and overtreatment in cancer: a prescription for change,"[2] suggesting that some cancers be reclassified, screened for, and treated as "indolent lesions of epithelial origin" (IDLE). The main point of the editorial author, Dr. Neal Bhatia, is that all skin cancer (SC) is cancer, defined by its pathogenesis not its behavior, and it destroys and kills.

Yet, we know SCs exhibit a very wide spectrum of behaviors. Many are asymptomatic, slow growing, and very rarely invade, destroy, or metastasize. Classifying these with aggressive cancers results in their overtreatment with increased, morbidity, mortality, and cost. For example, at the extremes, superficial basal cell carcinoma (sBCC) and nodular melanoma are both SCs yet exhibit marked differences in potential morbidity and mortality. To collectively group them as "skin cancers" downplays this difference.

In March, 2012, the NCI convened a group of more than 13 experts (not three as the author states) to assess this issue. They proposed reasoned, evidence-based, well documented recommendations and suggested that specialists in each organ system thoughtfully analyze and re-label indolent cancers as IDLEs. No cancers with more than a negligible propensity to invade, disfigure, debilitate, metastasize, or kill would be reclassified. They noted relabeling indolent cancers and cancer precursors as IDLEs would limit their unnecessary treatment when found during screenings and also remove medicolegal and ethical concerns about conservatively treating them. Yet, the editorial author characterizes these NCI recommendations as "irresponsible, short-sighted, and indefensible" further stating, "That squamous cell carcinoma, basal cell carcinoma, and melanoma are cancers is a medical fact…Skin cancers invade, metastasize, and kill. Skin cancers disfigure, debilitate, and kill. Skin cancers, left untreated, kill." This assessment and treatment approach that ignores the diversity in SC behavior is precisely what the NCI panel recommends be changed. Reclassification of indolent cancers has been done in other organ systems, resulting in significant reductions in unnecessary biopsies, treatment, and patient morbidity.[3]

The author further criticizes the panel's evidence-based statement that screening and early detection of IDLE lesions results in overtreatment and increased morbidity and mortality, despite this being well documented.[2,4-6]

Superficial BCC and squamous cell carcinoma *in-situ* (SCCis) merit consideration for classification as IDLEs. With certain exceptions, they do not need surgical excision. Topical therapies, cryotherapy, curettage, and photodynamic therapies are usually effective. Some cases do not merit any intervention when the patient has other more serious health concerns. Yet, in the USA, a great many of these growths are treated as aggressively as all other SCs, including with Mohs surgery. Certainly, should a lesion diagnosed as an IDLE recur or transform into a SC, it would merit reclassification and more aggressive treatment.

We know many dermatologists will object to reclassifying indolent SCs as IDLEs. Yet, if we do not take on this task and stop routine treatment of them with aggressive modalities, others will do it for us—with far less accuracy and to our detriment.

— Howard K. Steinman, MD
Anthony Dixon, PhD, MBBS

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2. Esserman, LJ, et al: Addressing overdiagnosis and overtreatment in cancer: a prescription for change. Lancet Oncol. 2014 May;15(6):e234-42.
3. Epstein JI, Amin MB, Reuter VR, Mostofi FK, and the Bladder Consensus Conference Committee. The World Health Organization/International Society of Urological Pathology consensus classification of urothelial (transitional cell) neoplasms of the urinary bladder. Am J Surg Pathol 1998; 22: 1435–48.]
4. Welch HG, Black WC. Overdiagnosis in cancer. J Natl Cancer Inst 2010; 102: 605–13.
5. Ransohoff DF, McNaughton Collins M, Fowler FJ. Why is prostate cancer screening so common when the evidence is so uncertain? A system without negative feedback. Am J Med 2002; 113: 663–67.
6. Cronan JJ. Thyroid nodules: is it time to turn off the US machines? Radiology 2008; 247: 602–04.

FDA Approves Keytruda for Advanced Melanoma

The FDA granted accelerated approval to Keytruda (pembrolizumab) for treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. Keytruda is the first approved drug that blocks a cellular pathway known as PD-1, which restricts the body's immune system from attacking melanoma cells. Keytruda is intended for use following treatment with ipilimumab, a type of immunotherapy. For melanoma patients whose tumors express a gene mutation called BRAF V600, Keytruda is intended for use after treatment with ipilimumab and a BRAF inhibitor, a therapy that blocks activity of BRAF gene mutations. "Keytruda is the sixth new melanoma treatment approved since 2011, a result of promising advances in melanoma research," said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Many of these treatments have different mechanisms of action and bring new options to patients with melanoma."

For expert perspective on the Keytruda approval, see this Month's edition of Oncology Watch on page 68.

Cynosure Acquires Assets of RF Medical Device Manufacturer Ellman International, Inc.

Cynosure, Inc., which specializes in laser- and light-based aesthetic treatments for non-invasive and minimally invasive applications, has acquired the assets of Ellman International, Inc. for approximately $13.2 million in cash. Cynosure also assumed certain contractual and current liabilities associated with normal working capital. Ellman develops, manufactures and markets advanced radiofrequency (RF) technology for precision surgical and aesthetic procedures and offers a line of aesthetic lasers. Ellman's current annualized revenue run-rate is approximately $25 million. The transaction is expected to be accretive to Cynosure's earnings per share by the first quarter of 2015.

"This transaction complements our brand portfolio, expands our market opportunities and enhances our recurring revenue stream," said Cynosure Chairman and Chief Executive Officer Michael Davin. "Ellman combines a 55-year history of innovation with an outstanding reputation for developing high-quality products that serve the needs of a global customer base. Thousands of physicians, cosmetic surgeons and medical aestheticians rely on Ellman technology. We believe these assets are an excellent strategic fit for Cynosure. Ellman's RF product line broadens our technology platform, while its aesthetic lasers allow us to offer a value solution at a different price point than our current offerings. We are pleased to welcome the talented Ellman team to the Cynosure family."

Ellman's product line encompasses multiple RF generators and single-use electrodes for aesthetic and multi-specialty surgical indications. Ellman's proprietary high-frequency, low-temperature RF technology is optimized for achieving surgical precision and controlled hemostasis.

"The efficacy of products such as Ellman's versatile Surgitron radiowave platform technology is supported by clinical validation in more than 300 surgical publications," Davin said. "What differentiates Ellman's platform technology is its ability to consistently achieve favorable clinical outcomes with minimal tissue damage, rapid recovery and less scarring."

In addition to Surgitron, the Ellman product line includes the RF-based Pelleve Wrinkle Reduction System, a skin tightening system for non-ablative skin rejuvenation that can be performed in an hour or less, is pain free, and is associated with no downtime. In February 2014, Ellman announced that its PelleFirm RF Body Treatment System had received FDA clearance for tissue heating and the temporary reduction in the appearance of cellulite. The device also is CE Marked for body skin tightening and cellulite reduction.

Ellman has approximately 100 employees, including an 18-person direct sales force in North America, a research and development team and distribution managers who oversee more than 65 international distributors. Cynosure expects to retain substantially all of the employees at Ellman, which becomes a division of the Company.

FDA Accepts Investigational New Drug Application for Alphaeon's Neurotoxin Evosyal

The FDA accepted the Investigational New Drug (IND) Application to conduct clinical studies for EVOSYAL, an botulinum toxin Type A neurotoxin that was acquired by Alphaeon last year as part of the acquisition of Evolus Inc. "Evosyal represents the state-of-the-art in both consistent manufacturability and potency as a 900 kDa neurotoxin molecular complex with high purity, both of which we believe will aid in achieving precise, predictable and long-lasting patient outcomes," said John Gross, MD, Chief Scientific Officer for Evolus. Alphaeon says it expects the initial clinical trial to be fully enrolled by the end of 2014.

Pacific Edge Granted US Patent for Melanoma Detection

The US Patent and Trademark Office granted Pacific Edge Limited, a cancer diagnostics company, US Patent Number 8,822,149 covering "Prognosis Prediction for Melanoma Cancer." The patent covers the technology being used to develop a melanoma prognostic test that will enable clinicians to distinguish aggressive and life threatening melanomas from those that are not as aggressive.

The test applies a gene signature to a tissue sample taken from the melanoma to detect its aggressiveness, allowing clinicians to prescribe the appropriate level of treatment. Specifically, the test in development identifies aggressiveness in Stage III melanomas.

Pacific Edge partnered with the Ludwig Institute of Cancer Research, the world's largest not-for-profit cancer research organization, to develop the technology. According to the company, this partnership has enabled Pacific Edge to develop its prototype product for detecting aggressiveness in Stage III melanomas.

The US is the third jurisdiction after China and New Zealand to grant patent protection for the 'Prognosis Prediction for Melanoma' test, which is in the development stage.

The melanoma test is one of several cancer products that the company has worked up to prototype level prior to focusing resources on the successful launch and further development of its Cxbladder technology for detecting and managing bladder cancer. Cxbladderdetect is now being commercialized in the United States, New Zealand, Australia, and soon in Spain. The second product in the program, Cxbladdertriage, is scheduled for commercial release in New Zealand later this year.

Promius Pharma, LLC: Finalist for PM360 Company of the Year Award

Promius Pharma, LLC has been named as a Trailblazer Company of the Year finalist by PM360, a publication that covers the pharmaceutical, biotech and medical device industries. Promius is one of three finalists in the category of Company of the Year: Specialty Pharma/Biotech.

"We are delighted to have been chosen as a finalist by PM360," said Raghav Chari, Head of Promius Pharma, in a statement. "This honor is a testament to the commitment and dedication of our team members across the globe. They continue to work toward our goals of delivering innovative products and services to meet unmet medical needs within medical dermatology. We feel privileged that PM360 would identify Promius Pharma as a finalist in the category of Specialty Pharmaceutical Company of the Year."

The PM360 Trailblazer awards have a tradition of recognizing outstanding achievement and innovation in healthcare marketing. The Company of the Year judging criteria includes: Innovation in Marketing and Advertising (pursuit of excellence and innovation across the board in advertising, sales, public relations, and communication); Talent Development (a record of attracting, developing, and keeping talent); and Social Responsibility (supporting patient access, civic and global involvement, and environmental consciousness). Finalists will be acknowledged and winners honored during a reception this month.

Modernizing Medicine Announces Inaugural EMA Nation Users Conference

Modernizing Medicine, Inc., creator of the Electronic Medical Assistant (EMA), announces its inaugural EMA Nation Users Conference. The conference will provide a venue for users of this specialty-specific electronic health record (EHR) system to network and learn how to use EMA's expanding capabilities for improving provider workflows and patient outcomes, and to address compliance mandates such as Meaningful Use and Physician Quality Reporting System (PQRS). Dr. Zubin Damania, more popularly known as the inspiring and energizing thought leader, speaker and entertainer ZDoggMD, will provide the keynote for the event, which will be held on November 7-9, 2014, at the Hilton Orlando Bonnet Creek in Orlando, FL.

Leio Corp. Offering Dispensing Solutions Online

An emerging service seeks to streamline skincare product recommendation and dispensing for medical practices. Leio Corp., self-described as a turnkey solution for medical practices, develops specialty cosmeceuticals and has implemented an online dispensing process that allows physicians to monitor patients' product use, track orders, and derive revenue from dispensing without allocating office space to display and storage.

Judy Lui, MD, co-founder of the DocSpa in Albuquerque, NM, says she discovered Leio Corp. when seeking a "scientifically based" skincare line for dispensing. "The company really works with a medical practice to protect the practice and physician," Dr. Lui says. Products cannot be purchased

online (leiocorp.com) without a physician referral code. That unique code is used to track sales and revenues for the physician. Participating physicians can log in for regular reports and to see if and when patients have ordered recommended products. Dr. Lui says this capability has allowed her to better understand patient needs. For example, if a patient only ordered product a few days before the follow-up appointment, she says she knows why they haven't seen results yet.

Practices can acquire products for on-site dispensing, as well, using the site to track and order inventory. They can also log on for training programs and use the Leio site for virtual events and education for their own patients, as well.

The DermaTend website touts the product as a surgical alternative.

Solace International Issues Recall of Dermatend Products

Solace International, Inc. is voluntarily recalling all lots of Dermatend Original and Dermatend Ultra in all sizes and dosage form to the distributor/wholesaler level. A mole should be removed under the supervision of a dermatologist. Dermatend is not FDA approved, thus has not been shown to be safe and effective for the uses suggested in the labeling. Using these Dermatend products instead of seeking medical attention could result in delayed diagnosis of conditions such as cancer.

Currently, the Dermatend Original and Dermatend Ultra products are used to remove moles, warts and skin tags. All units and lots are affected by the recall.

Solace International, Inc. is notifying its distributors/wholesalers by certified letter and is arranging for the return of all recalled products. Distributors/wholesalers that have Dermatend Original and Dermatend Ultra product should return all units and cases to Solace International, Inc. Consumers who purchased Dermatend Original and Dermatend Ultra to remove moles and warts should immediately discontinue use and consult their physician.

ASLMS will Host Two Laser Aesthetics Courses this Fall

In response to the success of its West Coast course, held annually at the Beckman Laser Institute in Irvine, CA, the American Society of Laser Medicine & Surgery (ASLMS) is initiating an East Coast Laser Aesthetics Course.

The courses are designed for anyone who desires to have a deeper understanding of how lasers and other energy-based technology works and then apply that knowledge to accomplish optimum clinical outcomes. It is made for individuals in the industry who currently use or are investigating the use of lasers and other light based technology in an array of clinical aesthetic applications. ■

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Alphaeon to Acquire Clarion Medical Technologies

Alphaeon Corporation, a subsidiary of Strathspey Crown Holdings LLC, and Clarion Medical Technologies Inc. entered into a definitive agreement for Alphaeon to acquire all of the outstanding shares and assets of Clarion, a provider of medical and aesthetic equipment and consumables in Canada, for an undisclosed sum. The acquisition is expected to close on or before September 30, 2014.

"Over the past twenty-five years, Clarion has shown consistent and profitable growth," said Robert E. Grant, CEO of Alphaeon. "This acquisition expands Alphaeon's geographic reach and provides early market experience with leading products from around the world, including Teoxane's full-line of dermal fillers, a strong energy device platform, and multiple ophthalmic technologies that provide patients optimal outcomes. We also intend to launch ShoutMD as well as our portfolio of Performance, Wellness and Beauty products in Canada through our unique digital selling approach.