I Market and Opportunity Analysis

Size and Regionality

The World Health Organization currently estimates that as many as 65,161 people die a year from skin exposure, primarily due to malignant skin cancers.[6] In 2002, 160,000 new cases of malignant melanoma were estimated to occur worldwide, and 41,000 deaths were reported as a result. [13] This deadly disease affects primarily Caucasian populations, with incidence rates of 20 times that of African populations.[1] The highest incidence occurs in Australia, New Zealand, The United States, and Northern Europe.

There are more than 1 million cases of skin cancer are diagnosed in the United States every year,[1] which translates to an estimated rate of 1 in 5 Americans diagnosed with skin cancer in their lifetime[2]. Although the majority of these cancers are basal and squamous cell carcinomas that are readily treatable, 1 in 32 men and women will be diagnosed with the more fatal version of skin cancer, melanoma.[1] This ranks melanoma as the 6th most common form of cancer in the United States,[13] and an estimated 121,840 new cases of melanoma will be diagnosed in 2010, 68,720 of which will be invasive.[13]

The raw numbers for Oceania (Australia and New Zealand) may appear less daunting, but the 20000 new cases of melanoma and 1250 deaths a year correspond to the world's highest incidence rates.[2] Cancer statistics from 2002 indicated an average prevalence of 37.7 cases per 100,000 men and 29.4 cases per 100,000 women in Oceania, locally reaching 65.3 cases per 100,000 in urban locations like Queensland, Australia and even 77.7 in Auckland, New Zealand.[27] These high rates make melanoma the third deadliest cancer in these regions, and have resulted in increased government intervention in melanoma treatments. Compared with 6.4 cases per 100,000 men and 11.7 cases per 100,000 women in North America,[13] the unusually high rates here are likely due to the equatorial climate, low ozone and increased recreational UV exposure.

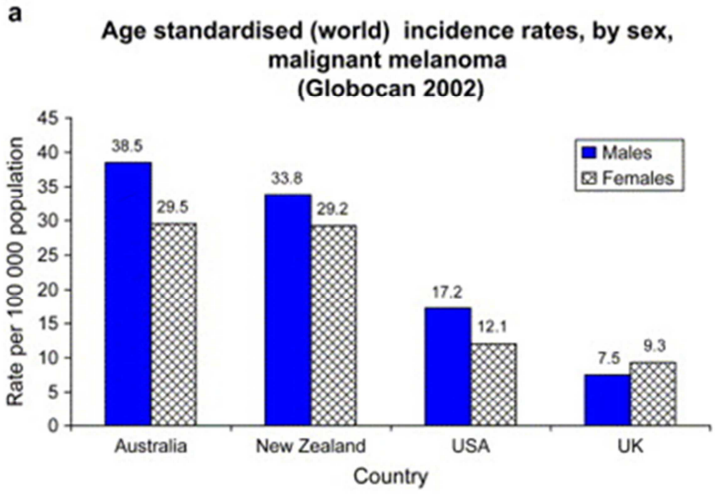

Figure 1: Incidences of malignant melanoma

In European countries, light-skinned vacationers often subject themselves to uncharacteristically high levels of UV radiation, and relatively low awareness has led to a lower melanoma survival rate (81%) as compared to the US (91%).[13] In lesser developed countries located primarily in eastern Europe, the survival rate for malignant melanoma is as low as 40%,

with speculative causes including low education, prevention, and poor treatment techniques.[13] As a result, in 2004 the World Health Organization (WHO) recorded 4,798 deaths in central and northern Europe and 2,256 deaths in eastern European countries.[6]

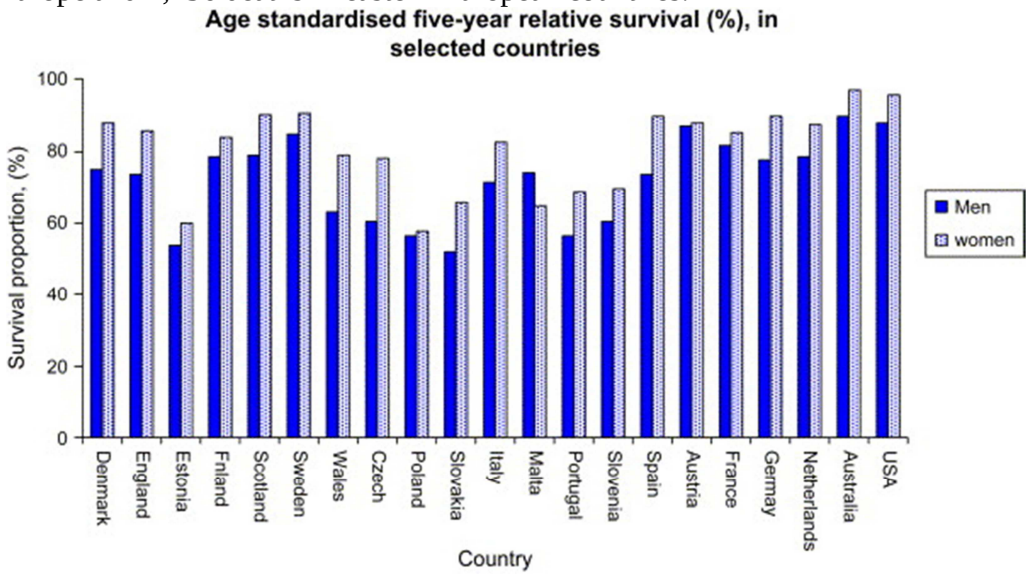

Figure 2: Five-year relative survival percentage for malignant melanoma

The physicians that treat these individuals must also be considered in the market analysis, as they represent the buyer of the machine. A cost-effective screening device seems most plausible in convenient Primary Care Provider (PCP) locations. As of 2004, there were 169,209 medical professionals practicing in the United States within fields relevant to skin cancer prevention, and over 6,766 medical centers according to the US department of Health and Human Services.[16, 2] These specialties included dermatologists, general practitioners, obstetrics and gynecologist specialists, and private-care physicians. In Australia, the total number of practicing physicians is estimated at 25,930, although the specialties of the physicians are unknown, and there are about 4000 listings in the Australian Health Directory for relevant physician practices.[28] It has also been documented that the average patient load for doctors in both Australia and the United States is around 20 patients per day, many of which are annual check-ups and include screening for colon and prostate cancers.[25, 26] Data for the PCP locations in Europe proved difficult to obtain given the varying political, economical, and geographical circumstances for each country.

Trends

The incidence of melanoma has more than tripled in Caucasian populations during the last 20 years.[13] Annually, this equates to an increase of 3-7% per year.[1] As a result, the current lifetime risk for developing invasive melanoma is 1 in 60, which represents a 2000% increase since 1930.[13] The age group experiencing the highest increase is men aged 55-64 (a 400% increase).[17] The rate of mortality associated with melanoma has also risen faster than any other cancer, resulting in the death of one American every hour, or 8,650 people annually.[1]

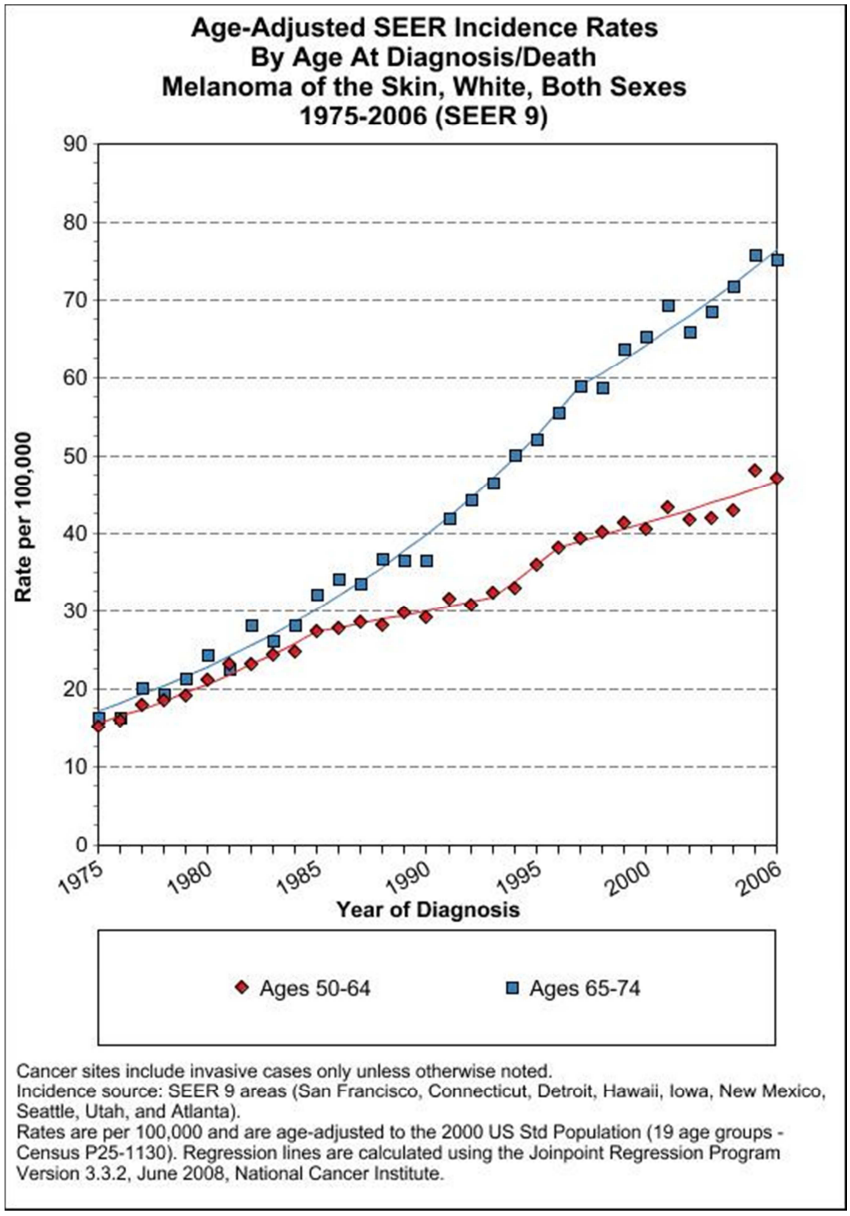

Figure 3: Incidences of melanoma in Caucasians

Literature has shown that the highest incidence of melanoma occurs in Caucasian populations aged of 50 and above.[5] Known as the "baby boomers" because of the disproportionate size of the demographic, this population is projected to grow from 29 million in 2004 to 40 million in 2014.[18] This growth should prompt concern over the incidence of melanoma, as 73.2% of melanomas were diagnosed between the ages of 50 and 74.[9] Older individuals are not only more likely to acquire melanoma, but also die from the disease, and it has been suggested in peer reviewed journals that "elderly persons should be a primary target for secondary melanoma prevention, including early detection and screening".[15] Although improvements in treatment have reduced mortality rates in populations aged 20-44 years, the mortality rates have risen 66% in Caucasian men aged 45-64 years and 157% in older Caucasian males (65+). [17] A higher incidence of health defects in general has been demonstrated in this age group, and governmental

strain to support this group is behind many legislative changes today. As a result, new technologies and products are developed daily to accommodate their needs and reduce the costs associated with providing medical care.

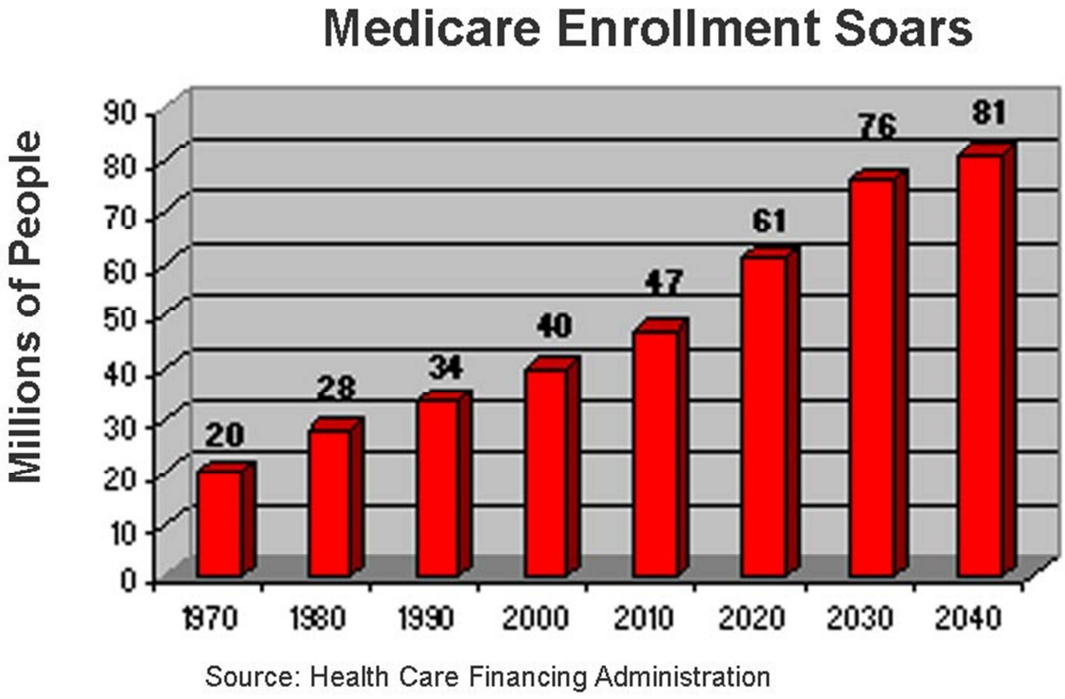

Figure 4: Medical care enrollment trends

The recent development of indoor, tanning salons has likely heightened the UV exposure to younger generations as well. Classified as a carcinogen by the US department of Health and Human Services, high pressure sunlamps may deliver as much as 12 times the annual UVA dose as compared to the dose normally received from sun exposure.[21] Thirty-million people tan indoors in the U.S everyday, 71% of which are women between the ages of 16 and 29.[22] This population is 2.5 times more likely to develop squamous cell carcinoma, and 1.5 times more likely to develop basal cell carcinoma.[23] As long as tanning remains fashionable, this trend will sustain itself and those that participate live at higher risk for skin cancer than the general population. As a result of this and other forms of recreational UV exposure, melanoma is the most common form of cancer for young adults 25-29 years old, and the second most common form of cancer for adolescents and young adults 15-19 years old.[4]

Need and opportunity

The most compelling aspect of preventative treatment for melanoma is not only its mortality, but also its curability. Studies have shown that roughly 84% of melanoma of the skin cases are diagnosed while the cancer is still confined to the primary site (localized stage), at which point the 5 year survival rate is 98.1%. However, 8-10% are diagnosed after the cancer has spread to regional lymph nodes or directly beyond the primary site and 4-6% are diagnosed after the cancer has already metastasized (distant stage) which have survival rates of 61.9% and 15.3% respectively.[9] It has been documented numerous times that the most effective method for

treatment of malignant melanoma is early detection, which is evident from the rapidly decreasing mortality rates associated with later stage tumors.

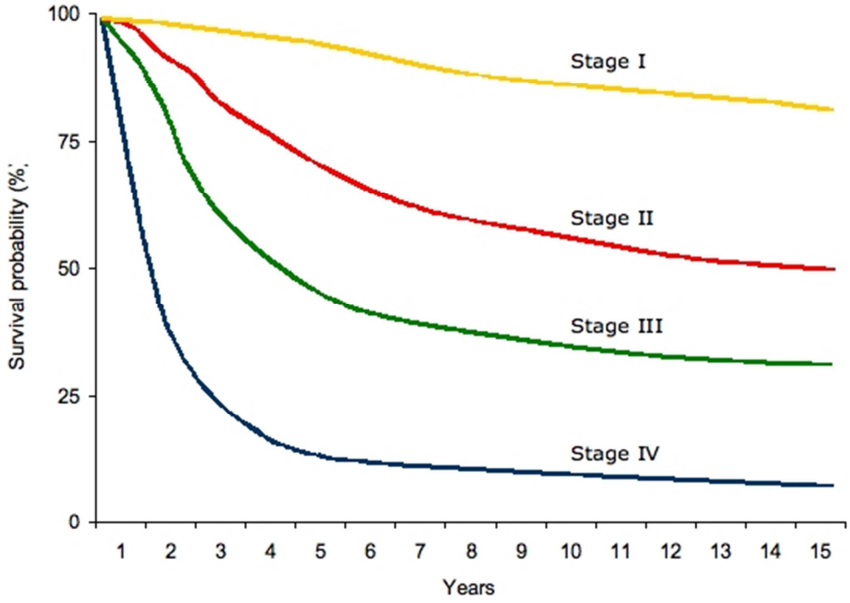

Figure 5: Probability of melanoma survival by cancer stage

The treatment for non-local tumors (regional and distant) exceeds 90% of the direct costs associated with treating cutaneous melanoma.[24] In 2004, the direct total cost was 1.5 billion, and is projected to reach more than 5 billion in 2010.[7,10] These costs are generally the result of chemotherapy or radiation treatments that are not only costly for the PCP, but also extremely invasive and painful for the patient as well. While relatively non-lethal, nonmelanoma skin cancers affect over one million Americans per year and are associated with potential disfigurations and impairment in health related quality of life. As a result, it ranks among the top 5 most costly malignancies for health care, an expense that has been observed in other countries as well.[12]

The mortality and cost associated with skin cancer treatment could largely be avoided with effective screening techniques that promote earlier detection of cancerous lesions. Several small-scale experiments and one larger effort in Queensland, Australia have demonstrated significantly lower mortality and increased local diagnoses of melanoma in populations that were part of a screening and education campaign.[30] However, the relatively low incidence of melanoma among the general population has prevented widespread screening processes from being accepted as cost effective. As a result, most care providers take a reactive approach in that suspicious lesions are most often examined as a result of patient complaint and biopsied in the same visit. However, this is not a perfect process, as patients commonly miss lesions on less visible portions of their body. A recent study showed that more than half of the malignant melanoma tumors were diagnosed by a full-body skin examination (FBSE) from a trained dermatologist, and were not part of the original patient complaint.[30] While the American Skin Cancer Society recommends that skin cancer related checkup be a part of any periodic health examination, very few undergo skin checks for a number of reasons.

Because there is insufficient evidence that screening for the general population is effective, public knowledge and education about melanoma is relatively poor. This means that the majority of skin examinations are of the patients own initiative, and many clinics do not offer dermatology services. Therefore, in order to receive a skin examination from a dermatologist a patient must often be referred to an independent office which may or may not be covered under the patient's insurance. After scheduling a second appointment at that office, the individual must travel to the office, check in, complete paper work, wait for the physician to be ready and then undress in front of an unfamiliar professional. The process is inconvenient, costly, and invasive for the patient, and not surprisingly relatively few individuals take this course of action.

Point of Entry

PCP offices in Oceania represent an optimal set of circumstances. Given the previously discussed incidence rates in these countries, the governments here have been proactive in education and screening efforts. Australian physicians also face a greater volume of patients than those in America, as evidenced by the number of physicians per 1,000 people (5.49 in the US vs 2.6 in Australia)[14]. In addition, the mixed public and private health care system facilitates the entry and purchase of medical equipment, especially those that lessen the burden on physicians. The relatively small geographic area also presents an attractive service area in which to base our operations, minimizing installation costs and customer support difficulties.

Increasingly, physicians in these regions are relied on to perform skin examinations. However, a study comparing diagnostic success rates showed that PCP's diagnosed melanomas with an 80% accuracy rating, which is significantly worse than dermatologists (89%).[31] In most clinics however, less experienced personnel administer FBSE's to lighten the load on overworked PCP's. Therefore, it is common practice for resident medical students with no dermatological experience to perform FBSE's, and a survey showed that even among certified nurses only 67% were confident in their skills administering FBSE's. [32]

Finally, to ensure efficacy of the system, our company will recommend screening in at risk individuals within these countries. In addition to evidence supporting screening of individuals over the age of 50, research has shown that people with more than 50 moles, atypical moles, or a family history of melanoma are at an increased risk of developing melanoma.[1] In addition, it has been demonstrated that one blistering sunburn or more than five sunburns at any age more than doubles an individual's chances of developing melanoma later in life.[19,20] By targeting patients that fit into this "at risk" population, the cost effectiveness and practicality of these screenings will likely be enhanced.

Although the United States represents an attractive market, the current health care reform and uncertainty regarding it is cause for concern in the medical field for the immediate future. However, it should be noted that approximately 758,658 US citizens had a history of melanoma in 2006, and those individuals as well as their families should be screened at least once a year.[9]

III Product/Service

Options

An advantage of the HelioSCAN is its versatile marketability, or the ability of the screening system to be sold as either a product or a service. One potential marketing strategy is selling the product directly to dermatologists. Although the referral process for dermatology clinics depends on insurance coverage, most patients must be referred by a primary care physician if

they want the visit to be covered. An advantage of selling the product directly to dermatology offices is direct access to the target customer (patients undergoing skin examinations). Currently, the general procedure for melanoma screenings consists of a visual examination of the skin by the physician and then a biopsy or complete removal of suspicious areas. Expert interviews have proven that dermatologists currently use various instruments to facilitate melanoma screenings. This demonstrates that this market is inclined to buy equipment that aids in diagnosis. However, selling the medical equipment to dermatologists may be unfavorable as competition already exists in the marketplace. These devices represent a potentially difficult barrier to overcome, which may deter selling this product to dermatologist. In addition, because the patient must be referred to a dermatologist prior to appointment, patient convenience of the (HelioSCAN) is ultimately compromised. Also, according to Dr. Robert Dellavalle, skin examinations only take a dermatologist 140 seconds to administer, so the physician benefit is minimized as well. Although the HelioSCAN initially requires physicians to review skin images, the ultimate goal of the technology is to be fully autonomous and incorporate image processing to determine changes in user's skin over time. The technology is thus an efficient dermatologist. Dermatologists seem to be reluctant of this technology as they view the system as a potential replacement. Dermatologists trust their own abilities and often resent external medical equipment altogether, meaning marketing the HelioSCAN as a product may not be the ideal strategy.

The HelioSCAN can also be sold directly to primary care or obstetrics and gynecology (OB/GYN) offices. Research has shown that many melanoma screenings are conducted by primary care and OB/GYN physicians, despite the fact that dermatology is not their specialty. , During expert interviews, general practitioners and OB/GYNs have expressed a degree of uncertainty in their abilities and willingness to perform proper skin examinations.. Furthermore, these physicians have shown interest in a product or technology such as the HelioSCAN that could aid in the screening process. Minimal deviation from routine and effort to incorporate the system into primary care and obstetrics and gynecology offices proves to be an advantage of this strategy as well. The HelioSCAN then becomes a part of standard procedure, similar to height, weight, and temperature measurements that are routinely taken during appointments. Proving the technology and reforming the examination procedures for general practitioners and OB/GYNs would be an enormous challenge. The median age of incidence for melanoma is 59 years, according to data from SEER Cancer Statistics Review from 2000-2006. Physical examinations are most often conducted on adults over the age of 50. Selling directly to primary care and OB/GYN offices thus provides direct access to the most susceptible segment of the population and our initial target customer. This strategy also allows access to other segments of the population and eliminates the need for a secondary appointment (with the dermatologist), saving both time and money for the patient and improving the efficiency of the screening process for the physician. However, expansion may be limited in that potential users of the screening system only have access if an appointment is made with the primary care or OB/GYN office.

Offering a melanoma screening service is an alternative marketing option. The primary strengths of this strategy are convenience and maximizing access to potential users. Our company would set up offices with HelioSCAN in convenient locations, allowing patrons to have skin examinations conducted on their own time without appointment. In this scenario, a physician or nurse practitioner would be hired for each facility to analyze the screenings and biopsy or remove suspicious moles on location. This maximizes efficiency for users as referrals

and secondary appointments are not necessary and wait times are limited. A clear disadvantage of offering melanoma screenings as a service is high start-up costs. The company is not only accountable for the costs of manufacturing and maintaining the HelioSCAN, but the cost of office space and medical professionals, as well. Furthermore, revenues are based on screenings alone, which could be an issue initially when the customer base is smallest. Compromising the low cost for screenings defeats one of the distinct benefits of the system. Another challenge of the service strategy is getting people to use the system regularly, especially without referrals from physicians. Depending on the location of the system, a lack of privacy may also deter usage of the system.

Operating costs associated with private offices are too high and represent a barrier for profitable business. In addition, concerns about patient privacy and the ability to attract a large enough customer base are difficult to assess, and uncertainty in the profitability of a private office building is too great to consider this as a viable business structure. In contrast, the direct access of PCP offices to our target market during annual checkups provides an attractive placement strategy for our device. Although the costs and time required to successfully launch a device are less attractive, they also serve as a barrier for other competitors catering to our target market. After considering these two alternatives, we have selected the sales of machines to PCP offices as the most viable option for our business.

Features and Benefits

Table 1 summarizes the key features of the proposed melanoma screening system. High-resolution, full-body skin imaging, and data storage allows both users and physicians to easily track even the most subtle skin and mole changes over a period of time. During expert interviews, physicians repeatedly stated that they do not have enough time to biopsy or remove all suspicious skin areas. The autonomy and speed of the system provides users with a comfortable and private environment that facilitates more frequent screenings and saves time for physicians. A built-in algorithm processes skin images and positively identifies melanomas. System software stores the images and creates a database of skin lesions that help improve the accuracy of the HelioSCAN, effectively making the system intelligent.

Features	User Benefits	Purchaser Benefits
High-resolution, full-body imaging	Comprehensive visual without appointment	Easy to examine patient skin remotely and at leisure
Image storage for chronological image sequencing and	Proof of abnormal changes in the skin for insurance purposes	Increased detection accuracy and screening efficiency
Autonomous	Increased privacy (comfortable environment), no appointment necessary	More efficient screening method, medical professionals do not have to rely on visual inspection and can examine images on own time
20 sec. screening process	Convenient, enables more frequent screenings	Time saving – medical professionals spend less time conducting screenings
Image processing algorithm	Gives users who have had prior screenings instant feedback on suspicious areas of the skin	Allows physicians to focus time on biopsies and removals of melanomas as well as other patient issues

Intelligent system that creates database of skin lesions for reference	Fewer false negatives	System improves with time
95% malignant accurate	Early detection	Lower cost/time associated with later stages of melanoma

Table 2: HelioSCAN features and benefits

Differentiability

Although the HelioSCAN is not the first medical technology offered that aids in melanoma prevention and diagnosis, the system's features and benefits distinguish the product from competitors, including visual skin examinations conducted by physicians, dermatoscopes, SolarScan, and Melanoscan. These products are all useful tools individually but fail to combine fast, easily accessible, inexpensive, and comprehensive melanoma screening techniques into one product.

II Industry Analysis

Industry Organization

The diagnostic imaging industry follows one main pattern of organization and that is from manufacturers to distributors to healthcare providers. General Physicians, in particular, are usually the first point of contact for a patient. For specialized care, one would typically get a referral from their general physician. Physicians are now more likely to be part or group medical practices, clinics, or integrated healthcare systems.

Value Chain Analysis

Value would be added with low costs…

Industry Structure

Barriers to Entry

The barriers to entry for the industry are very high. They include intellectual property, high switching costs, large capital investment, strategic partnerships, economies of scale, regulations, and agreements with healthcare providers. Most of the equipment used in the diagnostic imaging field has a patented design. Furthermore, the cost of buying one piece of medical equipment requires a large initial investment and high switching costs would be involved in purchasing and training for new equipment. However, relative to most medical imaging equipment, the cost of equipment for melanoma detection is low. Many of the companies in the medical imaging industry are large medical equipment or photography companies and can take advantage of economies of scale. A company that is already producing cameras can more easily produce medical imaging equipment at a low cost. Another barrier to entry is the FDA approval process. This ties in directly with whether or not the insurance companies will agree to cover screenings. While the barriers to entry are high, if a company can pass FDA regulations and get the go-ahead from insurance companies, it will provide a significant advantage to that company. Also, the fact that it is very difficult to prove skin cancer screening lowers mortality makes it difficulty to get such approval.

Competitive Environment

The medical imaging industry overall is dominated by a few large companies such as GE Healthcare. However, melanoma screening, in particular, is fragmented, with the majority of dermatologists performing Full Body Skin Exams with no equipment at all.
Low prices are important as many physicians have a spending limit and many others pay out of pocket for their medical equipment.

Competition

Direct competitors include other methods of melanoma screening. These currently include Full Body Skin Examinations (FBSE) by a dermatologist or general physician, use of a dermatoscope, the SolarScan device, and the Melanoscan device (all shown in the competitive matrix below). Indirect competitors include medical imaging companies such as Siemens and Carestream Health Inc., who could more easily develop and fund melanoma screening technologies. Future competitors include those who can tap into new technological breakthroughs and those who can combine cancer screenings into one system.

Competitive Matrix

Table 1, the competitive matrix, is found on the next page.

	Skin Examination by Dermatologist	Skin Examination by Other Medical Professional	Dermatoscope	SolarScan	Melanoscan	MelaFind	HelioSCAN
Features	Visual examination from the expert in field of dermatology	Visual skin examination from licensed physician with relevant experience	10X magnification, non-polarized light source, liquid between dermatoscope and skin, hand-held device	Produces digital pictures of suspicious moles/lesions, hand-held device	24 cameras, 48 images to be seen individually or as a mosaic, autonomous	Automatic image analysis algorithms and statistical pattern recognition, database of over 10,000 biopsied lesions, hand-held device	High-resolution photographs, mesh capable for 3D body imaging, autonomous, data storage for chronological sequencing, expandable database for intelligent system
Accuracy	50-75% accuracy; dependent on experience	50-75% accuracy; dependent on experience	Increases dermatologists' accuracy to up to 95%	Improves diagnosis by 23%	Set up an appt. with a dermatologist for a FBSE; cure rate of 99% after appts.	95% lower confidence bound for subgroups of pivotal study, specificity statistically significantly higher than clinicians	100% malignant accurate, limit false positives
Time	30 min. appointment (140 sec. for full-body exam., 72 sec. for half-body screening)	30 min. – 1 hr. appointment (screening time similar to dermatologist)	15-30 sec. per mole	30 min. appointment	10 min.	30 min. (examination and feedback)	30 sec. screening, 5 min. for feedback
Accessibility	Dermatologist only	GPs, OB/GYNs, NPs, PAs, etc.	20% dermatologists	Very few US dermatologists	1 office	Not available (under review with FDA)	Dermatology, OB/GYN, and primary-care clinics, hospitals
Cost to Consumer	$100-$150	Cost of appt. (typically co-pay)	Cost of appt.	$50-$150	$115-$150	Unknown	$15-$20
Cost to Physician	Profit	Included in cost for appointment (profit)	$200-$600	Unknown	Not for individual sale	Unknown	Out-of-pocket expense, $20,000
Usage	100% of dermatologists	Frequent but less often than dermatologists	Used by 20-25% of dermatologists	Mostly in Australia	One dermatologist with the scanner	Awaiting FDA approval for U.S.	Initially Oceania, U.S. after (need FDA approval)
Privacy	Low privacy	Low privacy	Low privacy	Invasive; doctor and digital photographs	Encryption and off-line storage	Invasive; doctor and digital photographs	Doctor-patient privilege; photos stay private
Insurance Coverage	Varies, more coverage for melanoma than screening	Often included in regularly examinations	Same as FBSE	No Specific Coverage	Coverage for personal or family history of melanoma	Unknown	No coverage; cheap

Table 1: Competitive matrix

Profitability

In order to get revenues in the early years of our start-up, we will launch in Australia, which has a high incidence of skin-cancer and a shorter approval process than the U.S. Australia's approvals go through the TGA (Therapeutic Goods Administration), which has an approval process of as little as 5 months. FDA approval, however, would be about 3 years. As we will have high research and development costs, early revenues will help cover some of the initial costs.

The Revenue Model

Using the bottom up revenue model, we have identified our customers and what drives their purchase decisions. Our first round of customers in Australia will consist of the 4,000 general practitioners and ob/gyn offices. From expert interviews we have learned that decisions in such offices are made in a meeting with all who practice in that office. The GPs or OB?GYNs take a vote on whether or not to purchase and then evenly split the cost of the machine. Those who have private practices typically bear the entire cost of the machine. Dr. Gary Garafa said he had recently made equipment purchases that were about $30,000. Thus we need to ensure the HelioSCAN has features that will drive doctors to a purchase decision. One main qualification is that the device has FDA or TGA approval. Other features include accuracy, convenience, reliable, and low up-keep costs.

There are 4,000 GP and OB/GYN offices in Australia. As there is no need for repeat purchases of the device, we estimate that there will be only one machine purchased for each office. We have set the price at $20,000. Financials of other medical imaging companies had an average margin of 60% (See Figure 1 in the Appendix).While this is closer to a 75% margin, we were concerned that pricing the HelioSCAN at $10,000 would be far lower than average industry prices, where as $20,000 would be more competitive pricing. The revenues from these numbers can be found in Figure 2 in the Appendix.

The first year of business will be dedicated to research and development of the HelioSCAN. The following year will not have revenues as we go through the TGA approval process. Revenues will begin in year 3, as we launch the HelioSCAN to GPs and OB/GYNs in Australia. We plan on gaining 20% of the Australian market in the first year, and growing this by 25% and 30% in the following years. These estimates are based on the growth rates of Sonosite, Inc, a comparable company seen in Figure 1 in the Appendix. This will help cover costs of further R&D and of clinical trials and FDA approval in the United States. This process of FDA approval will start in year 3 and on average would take until the end of year 5. Given this revenue model, we will not turn a profit until year 6, after FDA approval and the launch of HelioSCAN in the US, as this is a far larger market.

Key Assumptions

- TGA approval will take 1 year or less
- FDA approval will take 3 years or less
- We will get both TGA and FDA approval
- Manufacturing costs

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