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Strategies to Expand the U.S. Automated External Defibrillator Market

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
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Abstract

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by

Arturo Cervantes

MBA, Walden University 2009

BA, The University of Texas at El Paso, 1976

Proposal Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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Abstract

Despite defibrillation as the only effective treatment for sudden cardiac arrest (SCA), less than 15% of homes and public facilities have access to an automated external defibrillator (AED). In the United States, ineffective response to SCA cases occurring each year classifies it as a business problem for medical device manufacturing leaders, emergency responders, and bystanders. The purpose of this multicase study was to explore the marketing strategies AED manufacturing leaders use to expand their consumer customer base. Data were collected via in-depth interviews from a purposive sample of participants from 2 U.S. AED manufacturers on the east coast, 2 AED distributors, and 2 healthcare corporations in Texas, as well as a review of company materials. The framework for this study was product life cycle theory. Initial findings for expanding the U.S. AED market indicated that the market was not led by its manufacturers but by its distributors. This finding became an important theme noted from AED manufacturers in considering the consumer segment, an aftermarket from commercial marketing strategies. A common concern for the security of strategic marketing was evident across the AED manufacturer participants with reluctance to discuss business models and marketing plans. A congruent theme was the curtailment of open discussions regarding AED marketing strategies because of security and confidentiality risk. Also limited number of approved AED manufacturers by the Federal Drug Administration minimizes AED access. Residual outcomes include improving the quality of life for the aging population while reducing the loss of the lives and costs of healthcare. Social implications include preventing sudden cardiac death by providing more accessibility of AEDs to baby boomers.

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Dedication

I dedicate my doctoral study to my father, a gentle man with a relentless spirit to inspire his children in reaching the highest level of education. He was a mentor and a friend who taught me the meaning and value of servicing others in this life. He exemplified a value system rich in character and integrity as non-negotiable attributes. Sudden cardiac arrest (SCA) took my father's life.

My father was the light of my torch and my inspiration. He remains with me always and continues to guide me as I embark on a new journey of service. I am certain he would have been very proud to know my doctoral study was focused on improving U.S. businesses models and bringing positive social change.

Acknowledgments

I take this opportunity to acknowledge my sincere appreciation for the unselfish and tireless mentorship that Dr. Mike Ewald (doctoral study committee Chair at Walden University) has rendered. Without Dr. Mike's dedication and passion to helping students, I would not have reached my life's goal. I also want to express gratitude to my second committee member (SCM) Dr. Kelly Chermack. Dr. Chermack has been very instrumental in guiding and supporting me during the most difficult and critical time of my doctoral study (DS) journey. Also, a special thank you to my family and friends who have been a blanket of support and inspiration for helping me sustain my rigorous efforts and late hours of the night in finding my true north; and a very special thank you to my youngest daughter Jenean, a survivor from cardiopulmonary resuscitation at the tender age of 30 days by God's grace at my hands. You are my inspiration and have given me the strength to remain unwavering during my long journey toward the doctoral degree and have been my daily bread for this study. I pray for strength in my efforts to bring this research to market and the Lord to guide me to search new ways to help the medical device manufacturer leaders grow their customer base. The success of their customer base growth will mean the reduction of sudden cardiac deaths and infusion of healthy social change.

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Section 1: Foundation of the Study

The rising awareness of sudden cardiac arrest (SCA) and defibrillation in the United States are contributing to the growth of the defibrillator market. Sales of automated external defibrillators (AED) are increasing as part of patient monitoring service programs (Frost & Sullivan, 2012). Other contributors to the increase of awareness include more distribution of information and knowledge ascertained by the public of their effectiveness during critical minutes of resuscitation (AHA, 2014). The study includes exploring outcomes of public awareness and distribution of information regarding SCA.

In February of 2015, market researchers from Frost and Sullivan, Vision Gain, and Transparency, reported on the North American AED market. These market researchers estimated the market to grow at a compound annual growth rate (CAGR) of 6.8% from 2014 to 2019 in the prevention of SCD. Furthermore, the same researchers concluded the United States continued to have a larger share of the AED market with about 85% in 2013 (Frost & Sullivan, 2012). In North America, the top seven manufacturers in the external defibrillator market control approximately 89.9% of the market. Of the seven manufacturers, three are U.S.-based companies controlling 85% of the market (Frost & Sullivan, 2012). The three manufacturers are Pseudo AED U.S., Pseudo2 AED U.S., and Pseudo3 AED U.S.

The rising incidences of cardiovascular diseases (CVD) and SCA have various root causes. These causes include obesity, smoking, lack of exercise, and other heart diseases contribute to the increasing awareness of SCA and the life-saving potential of

AEDs (Heidenreich, Trogdon, & Khavjou, 2011). Businesses and individuals are recognizing the value of acquiring an AED and the importance of its accessibility through personal experience and published information from such sources as the American Heart Association (AHA).

Governance and federal compliances are a component of AED manufacturing and its public access. The AHA as well as state legislation such as the District of Columbia, have public access defibrillation statutes and regulations in effect in 51 U.S. Jurisdictions (Gilchrist et al., 2012). They advocate the installation of AEDs for public access, what is referred to as a public access defibrillator (PAD). Government campaigns, media coverage, Internet articles, and word of mouth, are some of the driving factors for market growth in small, medium, and large businesses as well as consumer markets.

The AHA (2014) determined that the survival rate of those treated with an AED, coupled with cardiopulmonary resuscitation (CPR), nearly doubles those treated with CPR alone. Timely application and general understanding of the AED by the user or bystander will yield a higher chance of survival (Yeung, Okamoto, Soar, & Perkins, 2011). Therefore, accessibility to an AED and bystander training during SCA incidents increases the chance of a victim's survival.

Growing direct sales channels and distributor network expansion by AED manufacturers are posting gains in the emerging U.S. commercial market segment. The top three AED manufacturers sold more AEDs to the commercial and consumer sector between 2013 and 2014 than any other year prior. Sales to corporate workplaces and public facilities have surged based on the growing demand and account for more than

40% of leading manufacturers' domestic AED revenue (Frost & Sullivan, 2012). U.S. medical device manufacturers' AED sales grew at a rate of approximately 70% (Heidenreich, Trogdon, & Khavjou, 2011). This percent is more than twice the rate of growth of the worldwide AED market. Market revenue for 2010 was $547.4 million and reaching $803.9 million in 2016 (Frost & Sullivan, 2011). While this is a substantial ground trend, AED sales are targeted to the business and public facilities markets.

Defibrillation is the only treatment for SCA victims during life-threatening cardiac arrhythmias, ventricular fibrillation, and pulseless ventricular tachycardia (Go et al., 2014). Automated external defibrillators provide an electrical shock terminating the arrhythmia and restoring the normal rhythm in the heart. Defibrillator devices are useful and the only means of preventing deaths during SCA (Go et al., 2014) for patients with unknown heart conditions. The number of SCA incidents continues to increase year over year.

The baby boomer population is aging in the United States alongside the rising cases of hypertension among adults 65 years and older. As more Americans continue smoking cigarettes, ingesting a poor diet, and curtailing their physical exercise, SCA numbers will trend upward (AHA, 2013). Because of these contributors and cardiovascular diseases, they become the major drivers of AED market growth. If medical device manufacturing and distribution marketing leaders design and execute marketing strategies and plans timely and effectively, they may position themselves for future growth in the customer base.

There are considerable costs associated with CVD. The direct and indirect cost of CVD and strokes in the United States for 2014 is $315 billion (Go et al., 2014). Coronary heart disease (CHD), in the United States alone, is costing $108 billion each year (Heidenreich et al., 2011). Coronary heart disease took one of every six lives in 2010. Per the AHA (2013), an estimated 620,000 Americans have a new coronary attack annually. A coronary attack is a first hospitalized myocardial infarction with 295,000 developing a recurring attack annually. The AHA (2013) estimated an additional 150,000 silent first myocardial infarctions occur each year. Every 34 seconds one American has a coronary event (Go et al., 2014). Every minute seven seconds one American dies of a myocardial infarction and nearly 400,000 out-of-hospital sudden cardiac arrests occur annually (AHA, 2014). Many deaths from CVD impact both the direct and indirect costs of caring for stroke and post SCA victims.

The U.S. Department of Health & Human Services (HHS) has a very honorable mission. Its priorities are based on enhancing and protecting the health and well-being of all Americans. Statistics from both the AHA and the U.S. Department of Health and Human Services confirm more than 900 deaths to sudden cardiac arrest each day (USDHHS, 2013). Public Access Defibrillation (PAD) programs, AED Programs for businesses, and other community-based chain-of-survival initiatives (Fothergill et al., 2013) assist SCA victims. Given the growth continuum in sudden cardiac death (SCD), there is a need for more aggressive marketing campaigns by medical device manufacturer marketing leaders to capture the commercial and consumer AED market. The goal of this

study was to explore strategic opportunities for medical device manufacturing company leaders to expand their AED customer base.

Background of the Problem

Having access to an AED anywhere is as important as the ability to apply it to prevent sudden cardiac death (SCD). The United States is the largest market for defibrillator devices and expecting to retain its top position through 2019. Notwithstanding its market position, approximately 350,000 Americans lives are lost annually to sudden cardiac arrest with 88% of all SCAs in the United States occurring at home and public facilities (AHA, 2013). Cardio Vascular Disease and stroke in the United States account for more than 930,000 deaths per year. The estimated cost is $315 billion (Go et al., 2014). The lack of AED programs and accessibility to public facilities, workplace, and homes is contributing to a $108 billion expense each year (Heidenreich et al., 2011). As a result of this large expense on SCA, medical device manufacturers' AED sales grew at a rate of approximately 70% (Heidenreich et al., 2011). This rate is more than twice the growth of the worldwide AED market. Despite this rate of growth, less than 34% of United States has public access to an AED, and less than 15% of private facilities have an AED (AHA, 2012). The AHA has previously addressed potential preventive initiatives for out-of-hospital SCA by way of CPR and defibrillation; Public Access Defibrillation (PAD); and bystander training.

In this study, I explored whether device manufacturing and distribution marketing leaders are maximizing their strategies on the AED customer base growth or leaving expansion opportunities in the U.S. home and public settings untapped. In addition, this

research includes consumer AED market opportunities, which are based on SCA statistics that indicate growth. In this study, I addressed research questions to the problem and discuss the business and social change implications of this research.

Problem Statement

Defibrillation is the only effective treatment for sudden cardiac arrest, yet less than 15% of public facilities and homes have an AED (Go et al., 2014). Medical device manufacturing and distribution marketing leaders are leaving an 85% potential market in the consumer segment unequipped (AHA, 2012). The general business problem is that some medical device manufacturing and distribution marketing leaders are not maximizing their sales potential in the U.S. consumer AED markets. The specific business problem is that some medical device manufacturing leaders have limited marketing strategies to expand their AED consumer base in the United States.

Purpose Statement

The purpose of this multicase study was to explore the marketing strategies medical device manufacturing company leaders use to expand their consumer customer base. The research method is qualitative with a multicase study as the research design. The population included medical device manufacturing marketing professionals from the top 3 U.S. companies, its distributors, and healthcare professionals. During the research and interviews, it was determined that while they were aware that the consumer base was expanding, their marketing strategies were not focused on this space.

A qualitative multicase study is a valuable method for research to develop theory, evaluate programs, and develop interventions (Baxter & Jack, 2008). The subset of the

sample was the company's consumer goods division responsible for the U.S. market. Expected outcomes of the research include convincing corporate leaders of their potential and financial gain. The sample may also contribute to business growth in the medical device industry and assist in reducing the $100 billion in annual expense for U.S. consumers (Heidenreich et al., 2011). As part of social change, the use of AEDs may prevent the loss of the lives of more than 350,000 SCA victims dying annually of which 88% are occurring at home and within public settings (AHA, 2013).

Nature of the Study

For this study, I used a qualitative, multicase study. The method identifies business issues across the population and not from a hypothesis (see Yin, 2013). As a form of inductive research, the qualitative approach was appropriate. This multicase includes medical device manufacturing company leaders and marketing professionals from various companies and healthcare professionals. The case study design assisted in my understanding of what marketing strategies managers use to grow their customer base. This qualitative case study and its design contributed toward a proposed solution for the business problem. The rationale behind the leader selection was to identify strategic decision makers and change agents from the manufacturing and companies. By identifying participants from the marketing, sales, medical, and technology organization, my expectation was to be then able to cultivate specific data from each with in-depth interviews.

The qualitative research method was appropriate for this study. Because my interest as a researcher was to secure reliable observations and gathering primarily verbal

data rather than measurements, I chose the qualitative method over quantitative and mixed methods. I also chose it because of the personal nature of this approach (Ritchie, Lewis, Nicholls, & Ormston, 2013). Qualitative approaches to information gathering focus on *why* and *how* questions and involve direct interaction with individuals in a one-on-one or group setting, whereas quantitative approaches focus on relationships between variables (Silverman, (2013). Research which typically involves counting and classifying as its attributes, is quantitative in nature. The Mixed Method Research blends both qualitative and quantitative attributes and approaches.

A case study was more appropriate for this research than phenomenology, narrative, grounded theory, or ethnographic design. A case study allows the researcher to conduct an in-depth investigation of a single individual, group, or event. During the exploratory research, it became evident that several individuals from different business groups would be needed. A multicase study design with the qualitative approach was determined to be the most appropriate design for this study. The research method determined the planning and strategy points. In-depth interviews were the most appropriate for collecting data on naturally occurring behaviors in their usual contexts. In-depth interviews were one method of data collection used in this study (Muskat, Blackman, & Muskat, 2012). In contrast, ethnographic is wider in scope and focuses on the sociology of meaning through close field observations of sociocultural phenomena. Phenomenology was also not appropriate for this study because it delineates itself from any recourse to theory, deduction, or assumptions from other disciplines. Grounded

Theory was also not a good fit because it focuses on research to understand the social and psychological processes that describes an event or situation (Marshall & Rossman, 2014).

Research Question

The research question for this study was: What marketing strategies medical device manufacturing company leaders use to expand their U.S. consumer customer base?

Interview Questions

1. Would you describe how your company's business model is open to partnerships that promote innovation?
2. How does the U.S. automated defibrillator market compare to others in the world?
3. How has your AED distributor network model evolved over the last few years?
4. How far are we from having an AED in every home?
5. How will first responder services be affected in case of SCA with hospitals moving from rural to metropolitan areas?
6. How is product affordability of AEDs for the aging senior consumer being addressed by your company?
7. Would you describe your company's perspective of AED Training Programs as a product value-add for market growth?
8. How have AED recalls influenced your product design?

9. Despite public awareness of CVD and large market share of AED sales in the United States, why does CVD still account for over 340,000 deaths outside of healthcare settings each year?
10. Would you elaborate on your company's involvement in medical device solutions for hospital treatment post-SCA?

Conceptual Framework

The conceptual framework for this study was the product life cycle (PLC) theory. The PLC theory pursues the notion of a product's market presence is like organic life (Nadeaua & Casselmanb, 2008). The four life stages of a PLC in which a product passes through are from inception to death. These four life stages include an introduction, growth, maturity, and decline which distinctively share more market characteristics with other products in the same stage than with itself at a previous or later stage. Per Michael Grieves (1971), these stages are where a product perish and become petrified. When infused onto organizational marketing strategies, PLC provides useful insight into competitive tactics, an alternate perspective on how to address issues of supply and demand, as well as those of time (Nadeaua & Casselmanb, 2008).

People manage organizations. Their influence and the decision-making culture they created come from their behaviors. In 1928, Marston wrote in the book, *Emotions of Normal People,* about how human behavior is not so cut-and-dry or black and white (Marston & Moulton, 2013). The author then went on to describe the various types of behaviors. While he did not write the Drive Influence Steadiness Compliance (DISC) theory of personality styles, his concepts behind DISC are the framework of the theory.

The theory later influenced the development of the actual DISC test (Marston, King, & Marston, 1999). The decision-making culture of the participants was explored.

Dominance styles are typically early adaptors and leaders driving the first-to-market culture in their respective organizations (Nadeaua & Casselmanb, 2008). The problem-solving process for medical device manufacturers in the United States requires a dominant approach by its marketing leaders to PLC. The dominant approach contributes to growing their consumer customer base. The Product Life Cycle may augment open business models. New business models allow outside ideas and technologies to be infused and propagate onto their products and services. The infusion may augment their economic potential (Chesbrough, 2012).

Definition of Terms

The operational definitions listed below are of technical terms, jargon, or special words, in alphabetical order. Also listed are citations of definitions from peer-reviewed articles/government websites.

Automated external defibrillator (AED): An AED is a computerized medical device which can check a person's heart as well as a potential shock it back to a normal rhythm (AHA, 2014).

Boomer: The word *boomer* refers to the Baby Boomer population of those born between 1946 through 1964. This generation is the Boomer Generation and portrayed as a generation of optimism, exploration, and achievement with increased educational, financial and social opportunities (Fingerman, Pillemer, Silverstein, & Suitor, 2012).

Cloud computing: Cloud computing is the use of powerful computing hardware for processing and leveraging high-speed Internet and software in smart mobile devices to gain ease of application management and ubiquity (Armbrust et al., 2010).

eHealth: eHealth (also written *e-health*) is a term for healthcare practice supported by electronic processes and communication, dating back to at least 1999. Industry leaders and marketing personnel use this term rather than academicians. The use of the term is in line with other *e-words* such as *e-commerce, e-business, e-solutions*, in an attempt to convey the promises, principles, the excitement around e-commerce (electronic commerce) to the health arena. The term's use is to account for the new possibilities the Internet is opening to the area of healthcare (Fox & Duggan, 2012).

mHealth Technology: Mobile healthcare technology is the same as mHealth. The use of mobile devices for health-related behaviors and human metrics (Brown, Yen, Rojas, & Schnall, 2013) is mHealth Technology. Health Informatics is MHealth Technology. This technology is used as a survey on ambient-assisted living tools for older adults (Rashidi & Mihailidis, (2013).

Myocardial infarction: Necrosis or destruction of a region of the myocardium caused by an interruption in the supply of blood to the heart is usually because of occlusion of a coronary artery. A myocardial infarction is a *cardiac infarction* (Meier et al., 2013).

Smarthome: Smarthome is the term used to describe a home built with technology infrastructure. The infrastructure may include telecommunication transport connectivity with wide broadband capacity. It may also include Ethernet wiring and power sources as

a premise to add technological applications. Telemedicine is one application used to monitor patients' vitals at home (Li, 2013). Voice communication and automated voice recognition applications on devices, will present a system of vocal order recognition in distant speech context. These features benefit the disabled and aging community at home (Portet, Vacher, Golanski, Roux, & Meillon, 2013).

Spoofing: Spoofing is the creation of TCP/IP packets using someone else's IP address. Routers use the destination IP address to forward packets through the Internet but ignore the source IP address. The destination machine uses the address to respond to the source (Jafarnia-Jahromi, Broumandan, Nielsen, & Lachapelle, 2012).

Sudden cardiac arrest (SCA): Cardiac arrest, also known as sudden cardiac arrest, is the abrupt loss of heart function in a person who may or may not have diagnosed heart disease (AHA, 2014).

Ventricular fibrillation (VF): VF is an arrhythmia most commonly associated with the onset of Sudden Cardiac Arrest (AHA, 2014).

Assumptions, Limitations, and Delimitations

Assumptions

An assumption is a supposition taken by a researcher as truth without actual verification or valid reference. Assumptions may carry risk in this study (Silverman, 2013). My first assumption was that the qualitative approach was the most appropriate method to explore the related factor. I also assumed that my selection of a multicase study design was an appropriate one for this study. Another assumption was the

participants selected would participate and provide honest responses (see Denzin & Lincoln, 2011).

In this study, I also assumed that, despite sales growth of AEDs, medical device manufacturing leaders are failing to equip the U.S. consumer markets proportionally and were contributing to slowing down the continued growth of SCD. Sudden cardiac arrest continues to be the number one killer of all combined deaths in America year over year. The assumption was that medical device manufacturer marketing leaders are not aware of the untapped emerging markets. Another assumption included the possibility that out-of-hospital defibrillator sales opportunities to the 65-year-old plus boomer population were the most abundant market for growth in the consumer space.

The assumptions of this study also included some medical device manufacturing and distribution marketing leaders not maximizing their market potential of their consumer goods and have limited marketing strategies to expand their AED customer base. Included in this study was a correlation between the high percent of U.S. homes and public settings unequipped with an AED and the 88% of SCAs occurring in American homes (AHA, 2012). The lack of AED sales to the U.S. homeowner will increase as more of the retiring boomer population grows and ages, proving all assumptions to be true.

Limitations

A limitation is a limiting condition and restrictive weakness. A limitation also lacks in capacity and the inability of the study (Locke, Spirduso, & Silverman, 2013). Several limitations existed in this study. The first included the number of available medical device manufacturers approved by the FDA of home AED models available for

sale without a medical doctor's prescription (Lenzer, 2004). The limitation is one manufacturer spanning 2 decades through 2010. In 2013, two other AED manufacturers were approved by the FDA, yet lack the manufacturing tenure of the top two manufacturers. Also, because medical device manufacturing and distribution marketing leaders have experienced high percentages of sales growth, they were, to an extent, myopic to the 85% marketing opportunity in the consumer goods sector. The 85% is the market growth remaining in the customer base citation?.

Medical device manufacturing and distribution marketing leaders determined their sizeable sales growth (Frost & Sullivan, 2012) as effective outcomes of their marketing strategies. Their sizeable sales growth, as the total potential for growth, may continue to be a misperception and prevent them from an open consideration of new marketing strategies. By not seeking to expand onto existing or emerging markets, a sales limitation continues to occur. The assumed limitation that the prospective manufacturer marketing leaders and its distributors, which are of European culture and business acumen, curtailed open business models to be infused was confirmed. Their marketing strategies do not allow infusing an open business model (Chesbrough, 2012). Marketing leaders continue to decide not to leverage the product life cycle onto their organizational marketing strategies to provide useful insight into competitive tactics (Nadeaua & Casselmanb, 2008). Using direct sales channels for the consumer market is where their ideology varied and their approach to market penetration, pricing, and retailers' product sales management. In turn, distributors and sales channels are those entities with open sales models, partnerships, and innovative initiatives.

Delimitations

Delimitations are boundaries that researchers impose to focus the scope of a study (Mitchell & Jolley, 2010). Some areas addressed include limited geographical location and a brief period to collect the data. Delimitations are within a researcher's control. Delimiting factors occurring in the study include the choice of objectives, the research questions, variables of interest, theoretical perspectives adopted by the researcher, and the population the researcher chooses to investigate (Simon, 2011). In using selected group of medical device manufacturing and distribution marketing leaders as a sample of convenience, as opposed to a random sample, delimited the choice of the population to investigate. The criteria in delimitating to a single firm were by leadership in U.S. market share in the consumer segment and approval by the FDA.

By delimitating time and duration to conduct this study, I attempted to control the scope of the study related to emerging markets driven by new technology conditions. The scope changed to some degree in the interval of the study. In this awareness, the research reflected data from the period and time of the interviews, corporate website, and data assessment (Coutts & Jann, 2011).

Significance of the Study

Contribution to Business Practice

There is a substantial business value in maximizing sales to U.S. consumers and emerging markets without AEDs or its bystander programs by the medical device manufacturers and its distribution channels in untapped markets. One of those untapped markets is the baby boomer retiree within the consumer market with only 15% having an

AED program (AHA, 2012). I explored potential marketing strategies to expand the untapped 85% AED consumer markets. The number of AEDs sales trends in the United States varies by researchers. Those researching AED trends from the largest medical device manufacturers worldwide estimated that in 2014, 775,000 units were sold annually to the public. These metrics represent an increase of approximately 30% per year (Markets & Markets, 2014). The market will reach $12.9 billion by 2019 at CAGR of 6.9% from 2014 to 2019 or approximately 912,750 units (Markets & Markets, 2014). The forecast period of 2014 to 2019 is based on the metrics from studies of the global defibrillators market. My intended contribution from this study was to surface segments of the consumer market where AED has its greatest potential for growth.

Based on this research, forecast dated as early as 2012 were already predicting annual revenue for the automated external defibrillator market by the end of 2015 to be $1.7 billion in the United States (Starr, 2012). The Global defibrillator market is expected to reach USD 15.75 billion by 2020 with a compound annual growth (CAGR) of 7.89 percent over the period 2014-2019. The U.S. market share represented less than 1% (Heidenreich et al., 2011) in 2011, yet Grand View Research (Grand View Research, 2015), forecasted to reach 10.7 percent share by 2020. This statistic supports the fundamental business problem and the opportunity to increase U.S. market share within the AED commercial and consumer goods by medical device manufacturer marketing leaders with marketing strategies contributing to effective business practices.

Derivatives and findings from this study may influence manufacturing and distribution marketing leaders to shift their marketing and sales strategies more

effectively. Marketing leaders' existing strategies, for most manufacturers in the United States, include sustaining 70% annual sales growth (Frost & Sullivan, 2011) in the existing markets, rather than exploring new marketing strategies and emerging markets in consumer goods of medical devices. Since the beginning of this study, new strategies have surfaced and will potentially represent a multibillion-dollar uplift in sales. Pseudo AED U.S., April 5, 2016, news release supports the AHA recommendations for wearable defibrillator use for the prevention of sudden cardiac death, is one example.

New product development and sales initiatives would accomplish what other researchers have not in this area of business. Other researchers have not explored emerging markets in the home and public settings, related to mHealth technologies. Other exploration for market growth opportunities may include the aging population from the U.S. baby boomers' era. This shift of focus and paradigm on manufacturing and distribution marketing leaders will bring meaningful insight and influence new strategies and customer base growth to medical device manufacturing companies marketing in the United States.

Implications for Social Change

The principle contribution toward positive change is to make a substantial advancement toward the improvement of human conditions. The improvement is by promoting AED programs for public access, home healthcare, out-of-hospital, and cardiac monitoring to prevent the loss of lives to SCA. The objective was to uncover AED manufacturer marketing strategies and its distribution channels that may yield just-in-time AED access and bystander assistance in the first four minutes a victim suffers

heart failure. Other authors and medical community leaders have addressed prevention by Emergency Medical Service (EMS) dispatching (Go et al., 2014), and other measures for cardiovascular disease. These measures include dieting, exercising, stress management, reduced tobacco consumption, and surgical procedures of Implantable cardioverter-defibrillators (Roger, Go, Lloyd-Jones, & Benjamin, 2012). While these measures contribute to the prevention of CVD, none addresses the prevention of SCD in the critical first 4 minutes that SCA occurs in a victim.

The true business application of this current study is to pivot the attention and resources toward solutions with timely responsiveness to the home and public AED programs during SCA. Social solutions or medical research of the root causes of coronary heart disease are more applicable to future cases and not for life-threatening solutions. Preventive medicine for individuals and organizational leadership will have a paradigm and ideology shift that will facilitate an opportunity for each to invoke positive change. The principle effect of the positive change is to make a substantial contribution toward the reduction of SCD victims and associated healthcare costs while contributing to the individual quality of life (Greengard, 2013). This paradigm shift and new awareness will help strengthen leadership accountability and innovation for reducing SCD and cost of healthcare in the United States.

A Review of the Professional and Academic Literature

The purpose of this literature review was to provide an overview of relevant, current, and previous studies, as well as a critical analysis and synthesis of various sources with a depth of inquiry. A critical analysis and depth of inquiry include the

increasing number of retiring and aging baby boomers to their homes and rural areas coupled with their increasing needs for medical services. The purpose of the analysis is to address issues surrounding the U.S. AED consumer market and its vast potential. This review includes an in-depth analysis of the trends in healthcare with the demands for hospitals to consolidate their presence and resources. The consolidation includes hospitals moving from rural areas to metropolitan areas in rendering medical services to the growing aging population.

The study includes a discussion of how this issue may create more market opportunity and AED manufacturers' marketing position. Included in the review will be the product life cycle (PLC) theory. The theory pursues the notion of a product's market presence is similar to organic life use of a dominance leadership style. In the review, I also addressed the rising cost of healthcare and the effect AED manufacturers potentially have in its reduction. Other issues and potential marketing opportunities are part of this review. The inclusion is specific to the dependency of accessibility and immediate medical attention and its relation to AEDs with the knowledge that 88% of SCAs happen at home and public areas. AEDs are an essential tool to restarting the heart and placement to cover the greatest amount of area and is the responsibility of the medical device manufacturers to provide approved models for home use. Automated External Defibrillator manufacturer sales and distribution of their AEDs to the consumer market is only 15% by all companies combined. There is an opportunity to explore the theory of the misalignment in their market strategies and demand in new markets. As a result, there is a curtailment of their business and social responsibilities. In this case study, I explored

AED coverage in out-of-hospital settings to determine its current and growing contribution to a $108 billion expense each year.

This literature review consists of scholarly and medical journals covering broad issues related to marketing and sales outcomes of AEDs by medical device manufacturers. Also included in the review are scholarly journals regarding strategic marketing for AED customer base growth in the United States. This review also consisted of trends in healthcare pertinent to demands forced on hospitals to consulate their presence and resources in metropolitan areas as opposed to remote or rural areas alongside associated industry issues. The literature review has content of trends and forecasts from medical journal literature on the baby boomer population, the aging, and its correlation with hypertension cases on the rise. The cases are among adults 65 years or older and the upward trend of SCA.

Governance by the FDA and state governments was part of the review exploring the contributing factors to bystander and training reticence. I also discussed research regarding the FDA governance and recall compliance as well as over-the-counter purchases and physician's prescription. Last, the literature review includes open business models, emerging technologies, and public awareness of AED programs.

I created this critical analysis and synthesis of various sources and content found in journals, reports, and scholarly books mainly through Walden Library of business management and technology professionals. I also used United States government regulatory entities published documents and other scholarly resources. Databases searched were: Business Source Complete, Lexis Nexus Academics, and Google Scholar.

Search terms included: *heart disease and stroke statistics, sudden cardiac arrest, life-saving AEDs, bystander and CPR, randomized response techniques, baby boomer, Association of American Retired Persons (AARP), defibrillation, Cardiopulmonary Resuscitation (CPR),* and *emerging technologies*.

My strategy in searching the literature included a clear understanding of the general and specific business problem of the study. I identified the subject matters associated with business, marketing, healthcare, aging population, emerging technologies, and governance. Ensuring 85% total of peer-reviewed sources with a minimum of 60 peer-reviewed sources for this literature review meets rubric criteria. Also, that 85% of the total sources have a publication dated less than 5 years from the anticipated completion date of study.

Within this doctoral study, there are 114 sources. Of the 114 sources, 107 or 93.8% are peer-reviewed. Seventeen sources that are more than 5 years of their published date to the date of this study were included. The total sources 5 years of their published date leave 97 sources dated 5 years or less of publishing from the date of this study, or 85.1%.

I have divided this literature review into five main subject categories. In the business and marketing management category, I explored the perceived causes of medical device manufacturing and distribution marketing leaders' failures in maximizing their market potential. I also explored the possibility of lack of awareness and use of an open business model to allow outside ideas and technologies. The potential use of an open

business model and its propagation onto their products and services, augmenting their economic potential is a part of this review.

Last, I explored the past and current marketing strategies used to determine the potential need to develop sustainable marketing strategies to expand their AED customer base. In the healthcare and retirement trends of aging boomer population category, I explored each trend to uncover root causes and potential pressure on the medical device manufacturers to develop new marketing strategies in the consumer market of AED home unit solutions. In the emerging technologies in medical devices category, I explored the rising cost of healthcare attributed to SCA. In the final category, I explored security, safety, and governance of AEDs.

Business and Marketing Management

PLC marketing with a dominance leadership style. Product Life Cycle theory is the notion of a product's market presence of a product is like organic life (Nadeaua & Casselmanb, 2008). The four life stages of a PLC in which a product passes through are from inception to death, where death is petrification (Michael, 1971). The four stages of PLC are an introduction, growth, maturity, and decline. These stages are distinct as they share more market characteristics with other products in the same stage than with a previous or later stage. When infused onto organizational marketing strategies, PLC provides useful insight into competitive tactics, an alternate perspective on how to address issues of supply and demand as well as those of time (Nadeaua & Casselmanb, 2008). People manage organizations and their influence, and the decision-making culture they created are from their behaviors. Marston (1928) in the book *Emotions of Normal*

People, wrote about how human behavior is not so cut-and-dried or black and white. He went on to describe the various types of behaviors. While the author did not write the DISC theory of personality styles, the concepts behind are the framework of his theory and led to the theory of the later development of the actual DISC test. These styles include dominance, influence, steadiness, and compliance.

The theory and evaluation regarding those leaders with dominance as the primary style with a potential blend of the other personality types affect their everyday actions. These actions influence a culture in an organization (Nadeaua & Casselmanb, 2008). Dominance styles are typically early adaptors and leaders driving the first-to-market culture in their respective organizations (Nadeaua & Casselmanb, 2008). Given this marketing theory and its relativity to the business problem, medical device manufacturers in the United States will need to be open for a new business model. Manufacturers' marketing leaders must lead with a dominant approach to PLC to grow their consumer base. Leveraging PLC through marketing leaders will open opportunities to alter the competitive landscape (Nadeaua & Casselmanb, 2008). Leading with PLC will also open business models allowing outside ideas and technologies infused and propagated onto their products and services. These efforts assist leaders in augmenting their economic potential (Chesbrough, 2012).

Based on the percentages of sales by these medical device manufacturers, sales of AEDs to the consumer market is only a 15% share of all companies combined. With 88% of SCAs occurring at home and public settings, combined with an 85% AED home market potential, the opportunity remains in applying the PLC marketing theory to solve

this business problem. The conceptual framework includes understanding the potential cause for the lack of some medical device manufacturing and distribution marketing leaders not maximizing their sales potential in the U.S. consumer AED markets. The framework also includes a conceptual element regarding the potential correlation between U.S. consumers and out-of-hospital facilities to AED programs. The correlation includes leaving U.S. consumers at home and other out-of-hospital facilities unequipped with AED programs. This void is an untapped market left open by AED manufacturer marketing leaders. By leaving this segment of the market open, it contributes to the increasing deaths associated with SCA and the financial effect on American businesses, its consumers, and their experience and sensory systems (Achrol & Kotler, 2012).

Marketing opportunities to expand the customer base. Publications from the AHA indicated that 88% of SCAs occur at home and in public settings (AHA, 2013). In the workplace, 3% occur, according to the U.S. Department of Labor – Occupational Safety & Health Administration (USDL-OSHA) records dating from 2003 to 2014. The remaining 9% occurring in other out-of-hospital locations. The marketing opportunity to expand the customer base is in the home consumer market. In the home is where 792 of the 932 daily deaths attributed to SCA in contrast to only 27 cases in the workplace with the remaining 81 cases in other out-of-hospital locations.

The Food and Drug Administration (FDA) has approved AEDs for home use without a prescription by four medical device manufacturers in 2013. Homes are the least equipped with AEDs or AED programs (Jorgenson et al., 2013) despite FDA approvals. One U.S. manufacturer with such approval occurred in 2010 (USDHHS, 2010). In 2013 a

second company received such approval and more throughout 2014. These FDA approvals, alongside the untapped potential customer base growth of the baby boomer consumer market, are evidence of a gap. This gap remains a considerably large marketing opportunity for medical device manufacturers.

Despite awareness of defibrillation being the only effective treatment for sudden cardiac arrest (Go et al., 2014) plans for a solution fail to exist. The AHA's initiatives in SCD prevention and the sales growth of AEDs to corporations and homeowners in America falls short of the needed coverage. Less than 34% of the United States has public access to an AED, and less than 15% of private facilities have an AED (AHA, 2012). With only 34% of public access to an AED, medical device manufacturing and distribution marketing leaders are leaving a 66% of the market unequipped. The results are similar for other consumers. The other consumers account for 85% of the U.S. market. Segments of this market are private facilities and homes do not own an AED. Trusted entities such as the AHA, AMA, Journal of Medicine, and by the medical device manufacturers, distribute public information of this nature.

The U.S. AED market opportunity for growth remains open. When compared to the global defibrillator market at $9.3 billion in 2012 (Frost & Sullivan, 2012), the percentage represents only a fraction of the global market. The expectation in the global market is growth at a compound annual growth rate (CAGR) of 6.2% from the year 2013 to 2019. Transparency Market Research (2012) forecasted an estimated value of $14.2 billion in 2019 North America, which includes the United States, Mexico, and Canada. This forecast represents the largest market for AED, followed by Japan and Europe.

North America and Japan forecasted to grow at a slower pace, primarily because of saturation in the market. The expectation in the Asian market is to register maximum growth over the next 5 years, based on the increasing installation of AEDs and rising prevalence of cardiovascular diseases. Market values between the United States, Canada, Mexico, Asia, and the globe may vary. As long as the potential of each respective market excludes the home model AED in their forecast, the U.S. market will hold its value.

The market for AED has become dynamic with companies in this segment adopting growth strategies of collaborations, agreements, and acquisitions. Emerging markets and out-of-hospital defibrillators represent abundant opportunities for stakeholders in this space. The AHA informed the public of decreasing survival rate. The public information illustrated decreasing survival rates to only 9.5% of the 359,400 out-of-hospital cardiac arrest incidents in 2013 in the United States. This decrease accounts 23.9% of adults and 40.2% for children in-hospital respectively for 209,000 incidents (AHA, 2012). These statistics includes African-Americans as they are almost twice as likely to experience cardiac arrest at home, work, or in another public location than Caucasians. African-Americans survival rates are half of Caucasians (AHA, 2013). African-Americans are much more likely to have diabetes, hypertension, a low educational level, low income, and lower mean levels of physical activity (Taylor Jr. et al., 2005). Women who are of Hispanic and African-American ethnicities are somewhat more likely than men to experience some of the other common symptoms particular shortness of breath, nausea/vomiting, and back or jaw pain. Symptoms as these are more difficult to determine while warning others that SCA is occurring (AHA, 2014).

Implementing open business models for AED manufacturers. This multicase study was on multiple leading medical device manufacturers; AED distributors and healthcare professionals in the United States. The study includes exploring factors motivating marketing leaders from the leading medical device manufacturers to seek assistance from experts to help develop more sustainable marketing strategies. These factors may include infusing an open business model. This portion of the literature review includes a discussion of the importance for medical device manufacturers to be in knowledge of the magnitude of the AED marketing opportunity. Although the big three U.S. manufacturers are augmenting their AED production, the question remains if they are effective in targeting the consumer segment and use of marketing strategies. The tendency of U.S. manufacturers to have proprietary business models and resident intellectual property is symptomatic and inherent to the manufacturing industry. These business models strengthen the company's market share with their own patented products. Automated External Defibrillator manufacturers are not an exception. Per Chesbrough (2012), innovation inefficiencies occur when companies operate in close business models lacking in exchange of technologies and intellectual property that is necessary to the industry and its consumers. Firms can awaken their dormant economic potential using outside-in perspectives and open to infusing outside ideas. By combining the use of internal technologies as well as a willingness to allow internal technologies to flow to the outside.

Rising cost and shorter timetables in design, production, distribution, and technology development are costly and time- consuming factors (Chesbrough, 2012) for

medical device manufacturers. FDA requirements and approvals are factors affecting AED manufacturers. FDA approval results in an additional delay if there is a history of recalls. D.M. Zuckerman, Ph.D. (2011); P. Brown, BS (2011); S.E. Nissen (2011), MD, reviewed the FDA approval process (2011). They concluded that medical devices passed through the less rigorous FDA 510(k) clearance. Medical devices comprise more than two-thirds of the products recalls by the FDA. This process harms patients or results in death. When devices were intentionally exempt from any FDA review were added to the FDA 510(k) approved and classified devices, they comprise more than 3 out of 4 of the high-risk recalls during the last 5 years. Their findings reveal important shortcomings in the current FDA device review system and its implementation that will require either congressional action or major changes in regulatory policy.

This FDA device review makes it increasingly difficult to support investments in innovation that result in added manufacturing pressures. These pressures include the cost of new product development and the expected revenue from sales to cover the cost of conducting business and achieving innovation. By applying an open business model, new brands of licensed technologies from other companies (Chesbrough, 2012) may generate millions of dollars in revenue and improve companies' expenses before interest, taxes, and amortization (EBITA). Open business models contribute to an increase in revenue. These business models were a point of discussion during the interview as part of motivating medical device manufacturers to consider an open business model.

Baby Boomer strong buying potential and greatest need for home AED solution. The baby boomer has a combined consumer buying potential of $3 trillion

(Parment, 2013). This constituency of consumers has the buying power and aware of more technical and digital devices and applications are part of the American culture (Behrens, Mislevy, DiCerbo, & Levy, 2010). Many retirees with financial resources are relocating to more remote and suburban locations. Given the trends of the aging and those of healthcare, the aging baby boomer may be at a higher risk than ever before.

American Heart Association's (2011) CPR statistics shows nearly 383,000 out-of-hospital sudden cardiac arrests occur annually and 88% of cardiac arrests occurring at home. Over 932 deaths occur each day to SCA (FDA, 2013) with approximately 792 occurring at home. If a home for the aging baby boomer is in a remote location, it implies a higher risk because home is where AED manufacturers have grown their customer base the least. There is less focus on marketing and sales strategies of AED home model, as well as minimal training programs by AED manufacturers to solve this issue.

Although AED manufacturers' marketing strategies include retail, over-the-counter, and Internet sales by direct distributors, the marketing gap remains in both commercial and consumer markets. The AHA estimates more than 95% of cardiac arrest victims die before reaching the hospital. The lack of market penetration of these markets reduces accessibility to an AED and decreases a victim's chance of survival. This reduction in accessibility to an AED reflects the weaknesses of previous studies and its outcomes.

Growing incidences of cardiovascular diseases and disorders, combined with the aging of baby boomer population entering their 65th birthday since 2011, are contributing to the growth of the U.S. defibrillators market. Concurrently, operating expenses

alongside market demands are forcing hospitals to consolidate their resources and physical presence in metropolitan areas as opposed to remote or rural areas. The aging population has the tendency to relocate to more remote areas (Oswald & Rowles, 2006) for peace and quiet, yet medical facilities are relocating to metropolitan areas. This relocation factor reduces first-responder and emergency resources to the aging population (Shabel, 2014). This remote living is especially concerning because these individuals depend on ease of accessibility and quick response for urgent medical attention. Retiring in rural areas for the aging boomers may not be a good option if these trends continue. This trend is an opportunity for medical device manufacturer marketing leaders to seize the trend by solving the issue using mHealth devices and technologies for the rural home, home healthcare, and retirement home facilities. One opportunity may involve the impact of mobile devices and how these devices are transforming healthcare and the development of new medical devices (West, 2012).

The market demands safe and easy to use features, as well as emerging technologies in out-of-hospital markets (Lewis & United States Food and Drug Administration, 2001). These features may be in concert with the boomer population which is more digitally centric (Oblinger, 2008). There are increasing trends toward installations of AEDs at workplaces by direct sales channels. No trends of AEDs home sales, installation, or training programs exist. This trend is a good opportunity for growth in the defibrillators market. With boomers, more digitally centric, coupled with no product recalls since 2010 (FDA, 2010), the opportunity for growth prevails.

Cost and risk of Healthcare in rural areas. As boomers begin to purchase retirement homes, the ideal landscape may include finding a rural area or small American town where they may find peace and serenity during their last years of life. Populations living in rural areas may have a risk for the aging and retiring boomers if they are not healthy (Shabel, 2014). Per Shabel (2014), the healthcare market demand for hospitals is forcing them to consolidate their presence and resources in metropolitan areas as opposed to remote or rural areas. This shift is especially concerning to the aging and boomer population because they depend on ease of accessibility and quick response as they may encounter cases in need of immediate medical attention. Some may advocate healthcare policymakers to the lobby and take action to ensure provisioning of medical resources to rural medical communities. This advocacy and awareness may be the opportunity for medical device manufacturer marketing leaders to seize the trend by solving with mHealth devices and technologies for the aging at home (Reeder et al., 2013).

Medical doctors and advocates such as Graham Nichol, Alfred P. Hallstrom, and Richard Kerber, have proposed defibrillation solutions in public places in which large numbers of older people are present (Nichol et al., 1998). Other experts in the field such as Myron L. Weisfeldt, M.D., Siobhan Everson-Stewart, Ph.D., Colleen Sitlani (2013) have concluded differently as their perspective is in medical terms. They evaluated out-of-hospital cardiac arrests in which 2042 occurred in public and 9564 at home during the same period of time. Their conclusion was that regardless of whether out-of-hospital cardiac arrests are witnessed by EMS personnel or bystanders and whether AEDs are applied by bystanders, the proportion of arrests with initial ventricular fibrillation or

pulseless ventricular tachycardia is much greater in public settings than at home. The incremental value of resuscitation strategies, such as the ready availability of an AED, may be related to the place where the arrest occurs.

The study underscores the number of cases at home and in need of equipment and bystander training, to be applied in much the same way as for the public, to prevent SCD. The AHA has also advocated Medical device manufacturing and distribution marketing leaders to assist with SCD prevention in this space. Nevertheless, manufacturers are still leaving their largest opportunity in the consumer market unequipped and at risk with an estimated 85% potential in the home and public settings (AHA, 2012).

Starts at home: An untapped potential market. Per the AHA (2014), 70% of Americans may feel helpless to act during a cardiac emergency because they either do not know how to administer CPR or an AED. Home is where 88% of cardiac arrests occur (AHA, 2013) and continues to be the alarming statistic. The FDA approved manufacturers to market an over-the-counter AED for home use (Mayo, 2015). This approval contributed to the overturning of regulation, which enforced the use of prescriptions. This regulation is no longer an obstacle to purchasing or using an AED at home.

Automated External Defibrillators are not prevalent in homes where the initial intent was to protect the aging or ailing individual. The home is where training and accessibility are at its minimum. Aging individuals is a potential market segment and issue unrecognized by medical device manufacturing and distribution marketing leaders. Statistics from both the AHA (2013) and FDA (2013) explicitly show more than 900

lives lost daily to sudden cardiac arrest. Yet initiatives to reduce SCD have not succeeded. Using Public Access Defibrillation (PAD) programs to assist SCA victims have not been an effective initiative. Focused and targeted marketing campaign by medical device manufacturer marketing leaders to capture the 88% of SCAs occurring at home, may be a more effective method. The limitations with bystander training support are a direct correlation to the statistics in the home and the lack of AED purchases by the homeowner.

A more relevant and progressive medical device industry focus is on implantable cardioverter-defibrillator (ICD) technology as opposed to AEDs. This issue, coupled with the medical industry's emphasis on preventive medicine, deters from AED and AED program advancements. By medical device manufacturer marketing, designing, and selling devices which provide medical assistance to patients with CVD history, the detraction from developments in the consumer AED space will continue. This strategy is reducing the potential to prevent SCD at home and provide first-responders with an AED solution with accessibility to the victim within 4 minutes in the critical minutes needed. This level of accessibility will take innovation and the ability to implement the technology through entrepreneurship and leadership. To summarize the opportunity, the combination of an open business model to seek new marketing strategies for the consumer goods sector may be the motivating factor. The motivating factor is for medical device manufacturer marketing leaders to seize the opportunity by growing their customer base with the baby boomer market.

Home AEDs. Home AED units are manual, mobile, with the ease of use built in averaging in price from $950 each for a low-end model to $1,200 to $2,900 for those with additional and automated features. Retailed by online distributors, pharmacies, and other medical device sales companies, their inventory includes well-known AHA endorsed brands. Their value proposition features manufacturer's warranty, turnkey solutions alongside the needed equipment to install AEDs at home. Training is an area which does not always come with the home AED solution and yet a critical part of a bystander assisting at home.

According to *The New England Journal of Medicine* (2011) in 7,000 people who had a heart attack, a study showed in which one group received family training in cardiopulmonary resuscitation and a 911 call strategy. In the same study, a second group received AEDs and training to use them at home. The authors addressed the perception of some bystanders who involve themselves with the use of the AED and not make the 911 call before engaging. After 3 years of follow-up, the authors concluded the researchers found the high-tech group had no better than the "call 911″ group because of bystanders' responsive attributes.

This study, supported by the National Heart, Lung, and Blood Institute, teaches doctors a few new lessons, aside from answering the primary question regarding survival in the two groups. The first lesson resulted in modern post-heart attack care had made considerable inroads in preventing late sudden cardiac death. Instead of the 4% per year death rate expected, the latest study documented sudden death rates closer to 1% per year. Only about a third of the deaths in this post-heart attack population occurred because of

rhythm problems treatable by the AED. Last, a third of the deaths were from non-cardiac causes.

In both groups, training was an important part of taking the proper action in an emergency either beginning CPR while calling 911 or using an AED. The importance of each situation is a trained bystander to use any of these options given the circumstances. If SCA was the emergency, the patient is without a pulse and an AED is the only device a bystander uses to bring back a victim to life (Capucci et al., 2002). By applying the AED within the first 4 minutes of the arrest, the survival rates for an SCA victim increase. If the emergency involves a victim who has stopped breathing yet has a pulse, CPR may be the best application.

The home continues to be a space where most SCAs occur and yet has the lowest percent of AEDs and trained bystanders. Retailers and online, direct sales companies are not providing the necessary marketing, training solutions, and awareness to motivate consumers to purchase AEDs for their home. The cost associated with the purchase of a new AED home model deters buyers from making this decision a priority. The Association of American Retired Persons (AARP) does endorse the authorized manufacturer of home AEDs. Despite the lack of endorsement, no joint marketing initiatives exist informing and promoting the critical need of owning and AED most especially for the boomers.

Cost-effectiveness and affordability of in-home AEDs. Direct sales channels to the consumer market include Internet sales, local pharmacies, and retail stores for those home model AEDs not needing a doctor's prescription (AHA 2014). Home and small

business model AEDs made by a U.S. manufacturer are readily available for purchase ranging from $900 to $2,900 as well as accessories as over-the-counter products at retail pharmacies. As early as 2004, the FDA allowed the sale of automated external defibrillators (AEDs) from approved manufacturers. During the same period, an approved class III medical device was the only one available for purchase with a prescription. Over-the-counter (OTC) sale approval of AEDs belonged to one manufacturer. The FDA approved a second manufacturer for an equal AED class, and the list continues to grow (Jorgenson et al., 2013). One criterion to secure FDA approval is the safety and efficacy of OTC AEDs purchased for the use at home. By 2009 many of the recall and safety issues previously reported had been overcome by the AED manufacturers. Notwithstanding, the need for an AED in the home to help prevent SCD remains a marketing opportunity for manufacturers already approved and dominant in the marketplace. While the largest opportunity in the consumer market is with the aging population, anyone is subject to an SCA. The benefit from purchasing, training on its use, and possessing an AED readily available during an emergency, is prevention. Defibrillation is the only effective treatment for sudden cardiac arrest (Go et al., 2014), and yet less than 15% of homes own an AED. The evidence of lack of sales and proliferation of the AED is that Americans are still dying annually of sudden cardiac arrest. It is more evident with 88% of all SCAs in the United States occurring at home (AHA, 2013). The opportunity to expand the market is evident with these metrics. Medical device manufacturers and its distributors will need to find ways to make home AED units more affordable; be more engaged in their direct sales network, and build

partnerships with vendors which core businesses in consumer products for the aging population.

AED distribution network and its products. Leading AED manufacturer use distributor networks as their sales footprint to capture volume of single unit sales. By surfing the Internet for distributors, leads to manufacturer landing pages and online stores selling their AED products directly. Distributors typically promote the implementation of the AED in dental clinics, medical facilities, schools, churches, police, and all public places (Palmero, Dotterweich, Lhotsky, & Walker, 2012). The marketed devices may include features such as the use audible speech commands and viewable signals to lead the rescuer through a resuscitation cycle that may include defibrillation and cardiopulmonary resuscitation (CPR). Certain units use rectilinear biphasic defibrillation waveform, and functions in either adult or pediatric modes and include both adult and pediatric defibrillation electrode pads.

Manufacturer designs and marketing include devising the AED with nervous rescuers' in mind because most may be experiencing it for the first time. Engaging bystanders willing to assist, AED features such as soothing voice, guides the rescuer through the crisis with simple step-by-step instructions is a help and a good marketing attribute for an AED. One important feature attracting prospective clients is the AED's ability to distinguish the force needed to compress the chest during CPR. Every person has a different weight and physical ability. The standard measurement of chest compression quality is not a force but the depth of the compression. These features provide ease of use and minimize error. All are good designs for ease of use and

expedites the process (Hallstrom & Ornato, 2004). The combination of the AED and CPR are the most effective in assisting a victim of SCA.

In a real-world situation when someone has collapsed, potentially from SCA, a quick installation of the AED will begin to analyze whether a shock is necessary. In 50% of the cases to resuscitate a patient, the shock is not required. Other designs include a one-piece electrode to accommodate the anatomical variation. Based on extensive research, some AED manufacturers meet the anthropometric chest characteristics of 99% of the population.

AED product attributes. During a crisis, simplified placement creates confidence and calmness during the critical minutes. By affixing two separate electrode pads to the patient's bare chest, may be confusing to a lay rescuer. Some manufacturers have simplified this step by guiding the placement of red crosshairs at the center of the patient's chest. Typically, the crosshairs have a hand-locator and two electrode pads falling naturally into an optimal position for both defibrillation and CPR. These features streamline the process and simplify the bystander's actions. All AED electrodes transmit defibrillating electricity into the patient through metal contact patch with a salt-infused gel applied to the patient's chest. Over time, the salt in the gel will corrode the metal and eventually compromise the electrode's functionality. Some AED manufacturers include novel electrode design includes a special barrier preventing most corrosion for five years or more (Fries, 2012). Last, defibrillators use lithium batteries are readily available in most stores. They typically are good for five years and included with the unit.

Other features found from different AED manufacturers include a simple to operate turns on with easy-to-use pull handle. These become standard features, and design brands come as ready-to-rescue features. The AEDs installed in the carrying case, and battery and pads installed on the device as standard features. Some smart units deliver maximum shock strength using a unique combination of high current to maximize effectiveness and a lower energy dose to minimize side effects harmful to a fragile heart.

AED quality control. Part of quality control, in most AED manufacturers, includes a 120-point test before it leaves the factory. Each AED conducts self-tests every single day. The AED performs over 80 different tests in all as well as the pads. The quick shock feature is a readiness test. This minimizes chest compression interruptions. CPR is more important to survival than previously realized, rapidly delivering shock after chest compressions are critical. This feature reduces the time between hands-off and shock delivery. The integrated pad test for their sensing application to the skin is their ability to sense from the cartridge and applied to the patient. The feature assures quality because it helps the first responder know what point the user is in the response process. Last, commonly graphics-based visual instructions with intuitive icon-driven operation and design must communicate instantly with minimum reading and interpretation. Users not familiar with the devices can follow the instructions easily. The quality control must yield the necessary metrics to pass manufacturer and FDA approvals (FDA, 2013).

Medical Device Manufacturing of AEDs for the Consumer U.S. Market. Boomers have long been the catalyst of the aging population by living longer (AHA, 2013), requiring quality of life and treatment option outside of the hospital, and medical

facilities when chronic conditions occur. Thus, home healthcare has required medical diagnostic and treatment devices with the capability to access remotely by sophisticated computer-controlled electromechanical measurement instruments. These medical devices located in advanced laboratories (Salditt & Bothell, 2004) are to accommodate consumer demand. As of 2005, medical device manufacturers have monitored the trend in medical devices for their design and manufacturing. Some trends include a tendency toward smaller, user-friendly, more portable products that require more advanced components. Innovation and scientific advances in manufacturing technologies and automation techniques add value to remain competitive. Medical products covering the range of patient monitors, drug delivery systems, therapeutic devices, and life assist devices all are shifting from the care of in-home medical personnel to medical facilities. The use of devices and telecommunication remotely connected provides access to in-home patients to these devices.

Aside from implantable devices such as an implantable cardioverter defibrillator (Bardy et al., 2010), new products are patient portable and patient wearable. Manufacturer designers are also responding to market demands for low-power components, long-life rechargeable batteries, rugged designs, simple user interfaces, and low cost (Salditt & Bothell, 2004). User interfaces may be an area of further research because many of the mobile applications and Internet connectivity is in telematics.

Medical device manufacturers marketing leaders and distributors of AEDs have an unlimited opportunity in both technology and design to expand in the consumer goods sector of this market. Coupled with an open business model approach, marketing leaders

will substantially expand their customer base and remain mindful of the statistics stated by the American Heart Association. Statistics includes an 88% of SCAs occurring at home and public areas (AHA, 2013). Only 3% occur in the workplace according to the U.S. Department of Labor – Occupational Safety & Health Administration (USDL-OSHA) records dating from 2003 to 2014. The remaining statistics include the 9% of SCAs occurring in other out-of-hospital locations. Based on the AHA (2013), the aging, which includes Boomers, are going into retirement requiring healthcare at home and not in the hospital or clinics. Because of this fact, medical device manufacturers of AED home units increase their total market position.

Healthcare and Retirement Trends of Aging Boomer Population

The aging population from the Baby Boom era is retiring. The Boomer Generation represents approximately 76 Million Americans born between 1946 and 1964 (Pruchno, 2012). The first of the baby boomers reached the retirement age of 65 in 2011 and the last group turning 50 in 2014 with women representing approximately 52% in both groups. Per AARP (2014), boomers will turn 65 at a rate of about 8,000 a day for the next 18 years. This sustained trend of a daily number of retirees will be the approximate number spending more time at home. Retirees may potentially be falling into the 88% of the SCA occurring at home with only a small amount of them equipped with an AED.

Given the large volume of Americans, the Boomer Generation will influence and transform the institutions of aging and many others in this era (AARP, 2014). What we do not know is whether boomers redefine this period because of their large number,

buying power, or management of the boomer market as they enter their aging years. This unknown factor may be the redefining point in which medical device manufacturing and distribution marketing leaders seize the opportunity to grow their customer base by a new approach and strategic marketing plan.

The growth of the aging population and SCA cases at home. Approximately 8,000 or rather 240,000 of these baby boomers retiring per month from the current U.S. population of nearly 320 Million (U.S. Census, 2014). Those boomers who are 65 years old or more represent nearly 33% of deaths from CVD. These deaths are occurring before the age of 75 years, which is well before the expected average of life 77.7 years (Lloyd-Jones et al., 2010). The 10-year window represents the boomer's life span from the time they reach 65 to their expected death at 75. The window provides the largest marketing opportunities to this consumer by AED manufacturers to grow their customer base. The life span for the 76 million boomers is 28 years of sustained customer growth potential. The first boomers born in 1946 reached age 65 and the last born in 1964 reached their 75th birthday. This statistic represents 28 years of profitability for any company marketing products and services to the Boomer Generation.

Emerging Technologies in Medical Devices

Medical Devices – Standardization of healthcare applications and decision making. In the beginning years of networking, various network protocols, telecommunications carriers and transport devices, computer operating systems, and data formatting varied. Military, private, and public networks in the world operated in their space. A similar case occurred with a technology platform. The principal was that by

agreeing on a single protocol, all connect and communicate with one another. This agreement was the marvel of how in 1997 Vinton G. Cerf. widely known as a *father of the Internet* and co-designer with Robert Kahn of Transfer Communications Protocol/ Internet Protocol (TCP/IP) and basic architecture of the Internet, orchestrated the idea. In much the same way, Albrecht (2012) recommended the standardization of medical applications. Under one platform in a domestic and international setting, all users have transparency of healthcare applications for trust and decision making (Rajagopal & Ramanan, 2011). This concept can yield many benefits to consumers and patients.

In the future, standardization will be more prevalent because intelligent devices such as smartphones and tablets integrate medical applications. Enhancing medical applications and devices augment patient safety and information assurances, as well as governance, are considerations for medical device manufacturer marketing strategies. It is important to engage end users during the development stages of their products. Deploying effective and transparent communication plans which inform and support product specifications, applications, and safety, are additional steps medical device manufacturer may consider in their portfolio of marketing strategies.

The AED and its measurement and locating limitation. Per the Food and Drug Administration (FDA), there are about 2.4 million AEDs installed and mounted in protective cases in private and public facilities across the country (FDA, 2013). The average AED has an expected lifespan of five to ten years. Most AEDs are not used within their life span. Not much wears out on these units. Manufacturers recommend a monthly check for operability and updates if they have digital intelligence. The AEDs

have the intelligent to notify when they have failed. The intelligence is an area of engineering improvement and part of my patent. The United States alone is losing more than 900 lives each day because of sudden cardiac arrest. Finding an AED using search and find technology, in the community, is important in preventing SCD. Per a study presented at the American Heart Association's Scientific Sessions (2015), most public automated external defibrillators are in buildings that are not open 24 hours a day. Thus, bystanders who may be near AEDs have limited access to the life-saving defibrillators in 21 percent of out-of-hospital cardiac arrests. In this study, researchers analyzed cardiac arrests that occurred within approximately 300 feet of a public AED.

Information gathered from studies conducted by the AHA (2012) requiring the installation of AEDs for public access defibrillator (PAD), is a driving factor preventing SCA fatalities to continue to grow. Legislation and advocacy are other driving factors in the prevention of SCA fatalities (Gilchrist et al., 2012). There is also the potential for closing the gap in time by using mHealth or AED technology to notify the 911 dispatcher. The SCA victim would have a chance of survival. Even if the technology existed, the average time of eight minutes for a 911 response unit to be on-site is longer than the life expectancy after an SCA (AMA, 2013). Last, there is also a gap in the actual measuring and analyzing the national coverage area and effect of bystander AED emergency response model. The existence of this gap makes it difficult for policymakers and the national healthcare community to manage.

AEDs and the perception of a benefit or a burden. According to the AHA's chain-of-survival process (Fothergill et al., 2013), someone should immediately call

emergency medical services, and a bystander trained in cardiopulmonary resuscitation (CPR) should assess the victim in need. If an individual shows no breathing and no pulse, the trained bystander should start chest compressions and ventilation such as CPR. The purpose of CPR is to deliver oxygen to the blood and to pump manually the oxygenated blood to the brain and other organs. CPR provides basic life support until advanced-life-support providers take over. If the victim is in cardiac arrest, performing CPR will not be enough. An AED is applied in the first four minutes of an SCA.

Security, Safety, and Governance of AEDs for the Bystander and First-Responder

The bystander is important to a successful AED Program. Per Go et al., (2014), EMS personnel treat approximately 60% of out-of-hospital cardiac arrests. These first-responders are medical personnel certified to conduct CPR and AED application when necessary. Trained and equipped Emergency medical service (EMS) personnel are vital for these types of emergencies. Their limitation as a first-responder is their inability to reach SCA victims in the critical minutes after SCA occurs. Their training in security, safety, and governance of AEDs protects their employers and themselves from potential negligence under standard conditions. Bystanders who first respond by coming to the aid of an SCA victim run various risks by engaging with the public. These risks are part of the 60% of out-of-hospital cardiac arrests. Not included in the Go (2014) study, is a metric recorded when delineating SCAs occurring in the public facilities from those occurring in other location and those with cases occurring at home.

To solve this issue, from a total out-of-hospital perspective, the AHA (2013) published an advisory. The advisory recommended improving bystander CPR/AED

programs in communities with low bystander response performance (Bradley & Rea, 2011). The effort was to evaluate the effect of community-based CPR training programs which in the United States ranged from 10%–65%. These initiatives are for the public and nonspecific to homes needing a very specific training and bystander CPR/AED program. While the intent was increasing cardiopulmonary resuscitation provision in communities with low bystander cardiopulmonary resuscitation rates, the program did not make a significant difference in the outcomes and metrics toward reducing SCD. The connection between out-of-hospital SCA incidents and the fact 88% of all SCAs occurring at home failed. The American Heart Association focuses on healthcare providers, policymakers, public health departments, and community leaders (AHA, 2013). Yet this organization remains an important part of the bystander program and a resource for those of us at home. Regulatory commissions, such as the FDA, have established safety-surveillance strategies that rely on physicians, healthcare institutions, manufacturers, and patients to report medical device failures and complications through the Medical Device Reporting system. This reporting functions as an additional step in governing critical medical devices such as external and internal defibrillators (Resnic & Normand, 2012).

Many traditional AED/CPR courses are provided by the Red Cross, the American Heart Association, private companies, as well as online courses on the Internet. These AED/CPR courses are for community and workplace participants like teachers, coaches, camp counselor, school bus drivers, personal trainers, daycare workers, babysitters, as well as construction workers and others. The courses vary in time to complete, although

most courses are approximately 45-60 minutes. The assumption that students trained under this AED/CPR course content are professionals would not be accurate. The assumption that a quick refresher AED/CPR course will provide expertise would also not be accurate. The assumed correlation between heart attacks and cardiac arrest with aging adults, or those with known heart issues, may be misleading. Unfortunately, anyone can go into cardiac arrest without warning. Another characteristic is not tailoring these training programs specifically to families with knowledge of how to be an effective bystander. The truth is that litigation is always a potential issue despite the protection of the Good Samaritan clause. Skilled personnel acting as bystanders, in best-performing nursing homes settings, are also sued. The hope is to subvert someday the capacity of litigation to provide incentives to deliver safer care (Studdert, Spittal, Mello, O'Malley, & Stevenson, 2013).

Saving a life is as easy as opening an automated external defibrillator (AED) located in almost every public building and workspace. The AED and a bystander are the only medical solutions known to resuscitate a victim during SCA (Go et al., 2014). As previously mentioned, 88% of all out-of-hospital SCAs occur at home (Go et al., 2014). Yet less than 15% of homes have an AED (Go et al., 2014). Current research indicates the chance of surviving SCA improves by 70% by applying an AED within the first 3 to 5 minutes (Go et al., 2014). In these few minutes, the best resources and trained first-responders do not make it in time.

In the athletics arena and school campus settings, it is recommended by the American Heart Association (AHA, 2013) that AEDs be part of an Athletic Trainer's

emergency action plan. Action plans as these alongside classroom-tested kit empowers educators to teach CPR to hundreds of students. In most university campuses, the athletic trainer has an AED accompany them with additional units accessible on campus. According to the American Heart Association, more than 250,000 people die every year from sudden cardiac arrest. Up to one in every five of those deaths is preventable with a defibrillator. Campus personnel and athletic department trainers effectively apply AED and CPR within 3 to 5 minutes if they are the first person on the scene. In the same way, a home AED must include an AED program with the AED unit. Automated external defibrillator manufacturers have the option of initiating solutions. The chain-of-survival community is one option which provides resources and entities such as the Red Cross, and the AHA.

Transition and Summary

In Section 1 of this study, I covered the fundamental issues surrounding the limitations of current marketing strategies by medical device manufacturing company leaders to expand their U.S. AED customer base. I also discussed its relationship to the market potential and several U.S. homes without (Frost & Sullivan, 2012) AED programs. The research study statement underscores the general business problem with medical device manufacturing and distribution marketing leaders not maximizing a potential in the U.S. consumer AED markets.

The specific business problem describes a shortcoming by the medical device manufacturing company leaders possessing limited marketing strategies to expanding their AED consumer base. An overview of the issue described in this study includes

potential reasons and repercussions. The overview includes deprivation of just-in-time defibrillation to SCA victims. Various literature review and data uncovered several research options. One option is the qualitative approach to capturing in a multicase study manufacturer marketing leaders' business model, behaviors, and marketing strategies. This approach infuses and influences an open business model and focus on the home AED as a target market. In Section 1, I also covered relevant past and current studies surrounding the concept AED programs, regulatory issues, and its relationship financial performance of AED manufacturers and healthcare cost savings. Section 2 includes the purpose statement, role of the researcher, participants, as well as the research method and design. Section 3 includes the analysis, discussion of results, as well as potential implications for business practice and social change.

Section 2: The Project

Since 2010, medical device manufacturing and distribution marketing leaders have experienced a substantial increase of AED sales in the U.S. market (Frost & Sullivan, 2012). This experience has predominantly been from an increased public awareness of SCA, defibrillation, and a ubiquitous need across community landscapes for accessibility to AEDs and its training programs (AHA, 2014). Interest by various stakeholder groups regarding preventive health against CVD and CHD have all contributed to the increase in sales by pursuing their respective needs and initiatives. Stakeholders include companies seeking their interest in safeguarding their employees; U.S. government's initiatives of AED placement in public facilities; and the public with community-based PAD programs.

Despite public awareness and programs throughout the medical community and public sector, some medical device manufacturing and distribution marketing leaders are not yet maximizing their sales potential in the U.S. consumer AED markets where most SCAs occur. The lack of maximizing their sales potential is creating an abundant opportunity for a nonservice customer base growth. It appears that medical device manufacturing company leaders may have limited marketing strategies to supply the expansion of the AED customer base.

Through this multicase study, I explored marketing strategies and business models in an effort to uncover medical device manufacturing company leaders perspectives on these concepts and approach to expanding their U.S. AED customer base. I also explored the market potential of U.S. unequipped homes public settings (Frost &

Sullivan, 2012) with AED programs. Outcomes from this research may include the uncovering of new marketing strategies and business model opportunities for AED manufacturers. Other outcomes may include identifying emerging AED markets, improving survival rates, and improving the quality of life for SCA victims. Other areas explored include emerging technologies and contributing towards reducing healthcare costs.

Purpose Statement

The purpose of this multicase study was to explore the marketing strategies medical device manufacturing company leaders use to expand their consumer customer base. The research method is qualitative with a multicase study as the research design. The population included medical device manufacturing marketing professionals from the top 3 U.S. companies, its distributors, and healthcare professionals. During the research and interviews, it was determined that while they were aware that the consumer base was expanding, their marketing strategies were not focused on this space.

A qualitative multicase study is a valuable method for research to develop theory, evaluate programs, and develop interventions (Baxter & Jack, 2008). The subset of the sample was the company's consumer goods division responsible for the U.S. market. Expected outcomes of the research include convincing corporate leaders of their potential and financial gain. The sample may also contribute to business growth in the medical device industry and assist in reducing the $100 billion in annual expense for U.S. consumers (Heidenreich et al., 2011). As part of social change, the use of AEDs may

prevent the loss of the lives of more than 350,000 SCA victims dying annually of which 88% are occurring at home and within public settings (AHA, 2013).

Role of the Researcher

The data collection process for this qualitative study includes interviews with AED manufacturing marketing, distribution leaders, and healthcare professionals, as well as reviews of companies' website material, analyzed data, and the findings. The purpose of the interviews was to gather objectively relative information and have firsthand knowledge from the interviewee regarding the case study (Lawrence & Tar, 2013). My role included developing and planning the interview from interfacing with manufacturer leadership and understanding their operations model. Their PLC and business model was also included in my interviews. During the interviews, I ensured correct scheduling as well as playing the role of interviewer by contacting their respective public information officer (PIO) or administrative assistant in advance and providing pertinent information.

Throughout the data collection process, I focused on the fundamentals of the research in uncovering answers to questions and collecting the evidence while producing new findings not determined in past studies. I also considered marketing applications after this study. The qualitative research was effective in ascertaining company's core values, business acumen, and awareness of market opportunities. However perspectives on infusing an open business model in the organization were not received well by the manufacturer, yet effective with the distributor network leaders and healthcare professionals.

As the researcher, I followed ethical procedures and protocol congruent with Belmont's Report. The Belmont Report published July 12, 1974, and based on the National Research Act (Pub. L. 93-348), signed into law and creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report drove changes to the Commission by identifying the basic ethical principles and emphasizing their importance of conduct by biomedical and behavioral research (Faden et al., 2013). The specified conduct and behavior was regarding human subjects, and it included guidelines to assure research by these principles. Important and prevalent situations include medical, nursing and caregiving settings (Sims, 2010) where ethics in healthcare are especially necessary.

I remained objective during this research to ensure a scholarly approach to the study of authentic interest, motivation, inquisitiveness, and commitment to uncovering the data objectively. I secured objectivity by focusing on the business problem, adhering to the research process, and retaining an outside-in perspective during interviews with participants. The researcher has an integral role in the process and is the main instrument of data collection (Bansal & Corley, 2011). The data collected from the research was analyzed and compiled for independent interpretation. By following this plan, I ensure the quality of research was conducted and free of bias and personal views.

The interview protocol is an important tool for mitigating bias and viewing data without a personal influence. The interview protocol helps one retain an outside-in perspective during interviews. I utilized an interview protocol as a tool to assist in reducing biases. An interview protocol is a comprehensive instrument that researchers

use to assist with data collection (Jacob & Furgerson, 2012). The protocol included interview questions with procedural guidelines to assist participants in conducting the interview from beginning to end. By following the interview protocol, I achieve consistency across all interviews.

As the researcher, I focused on becoming knowledgeable of the facts during the study. I remained cognizant of the importance and potential of infusing of new marketing strategies and open business models for AED manufacturers and their distributors to expand their customer base. As a part of the study, I plan to acknowledge potential implications for positive social change. The implications include the potential to save the lives and quality of life for over 350,000 SCA victims dying annually (AHA, 2013). Other implications include reducing annual expense for U.S. consumers (Heidenreich et al., 2011).

Participants

In this qualitative study, I chose a multicase study of the dominant leaders of medical device manufacturers and have selected three PseudoAED, U.S., AED distributors, and healthcare professional companies. I included six participants from the manufacturers, distributors, and healthcare professionals. The participants represented three important areas, which include marketing, sales, and product development from their respective consumer goods division. The participants chosen were the most eligible to discuss the infusion of new business models. As marketing professionals, they influence any change in marketing strategies. By following the respondent selection process, it assisted me in achieving triangulation by interviewing, assessing collected

data, and exploring company's website from multiple corporations and their perspectives on the general and specific problem stated in this study.

Study participants, with the unique and specific ability to provide relative and quality data, contributed answers to research questions during data collection (O'Reilly & Parker, 2012). Their contribution assisted in reaching the point of data saturation (Marshall, Cardon, Poddar, & Fontenot, 2013). Achieving saturation included data review and new relevant information, perspectives, and experiences no longer appearing from additional interviews (O'Reilly & Parker, 2012). Gaining access to these marketing leaders was very difficult in part because some were still undergoing their PMAs while others very leery of releasing sensitive marketing information that would end up with their competitors. My initial approach was to use traditional and professional forms of communication.

Other strategies included social media connections and professional organization networking. However, they were not very effective. A last and final attempt was leveraging their social responsibility for companies of this size as part of their operating business and community outreach model. By identifying their community initiatives, it reminded them of their company's mission statement and thus helped me to connect and began collaborating with senior leaders and other company employees. In contrast, leaders from the distribution channels and healthcare professionals were very open and receptive.

The initial interface established contact with potential participants and company employees. After establishing contact, I remained mindful that they are employees of

high responsibility and are decision makers in their respective companies. The selection of these participants was an important and an integral component of the research process, as well as remaining objective in their selection and maintained a perspective in mitigating personal bias. In forming conclusions from the data collected from these participants, there were no limitations in participant selection or influence to the quality and outcome of the study (Reybold, Lammert, & Stribling, 2012).

The choice of the participants from multiple medical device manufacturers, distributors, and healthcare corporations created a unique representation of senior-level marketing, sales, and product development leaders responsible in some capacity for the U.S. AED consumer market. The research questions previously prepared for the interview were consistent with the protocol. The study included researching participants' current and potential strategies for emerging markets. The purpose was to explore their ability to contribute to the development of a new customer base in the AED marketplace. By exploring their plans for expanding public, consumer, and private accessibility, there is a likelihood a contribution to positive social change will arise. Most of the previous studies, in this space of study, have not included the aging population entering retirement as an emerging market or specific focus on in-home AEDs as a gap in market need or demand.

The qualitative approach yields the criteria of objectives and personal interactions, which were needed during information and data collection. The qualitative information will consist of personal interviews, assessment of collected data, and documents review to address the specific business problem. By probing and exploring the

company's perspective on open business models, it yields the necessary data for this study. Exploring the company's existing marketing strategies and plans with a medical device manufacturing company and distributors' leaders to expand their customer base was an important objective.

Research Method and Design

An exploratory, multicase study design with the qualitative approach was the most appropriate design for this study. I chose the qualitative method over quantitative and mixed methods because of the personal nature of this approach (Ritchie, Lewis, Nicholls, & Ormston, 2013). The qualitative research method was appropriate for this study. The research method determined the planning and strategy point at which medical manufacturing and distribution marketing leaders decide, or not, on AED products and marketing strategies of their AED home units. The further determination to address customer base expansion, based on current and emerging markets, was one of the results. A case study was more appropriate for this research than phenomenology, narrative, grounded theory, or ethnographic design. In-depth interviews were the most appropriate for collecting data on naturally occurring behaviors in their usual contexts. In-depth interviews were one method of data collection used in this study (Muskat, Blackman, & Muskat, 2012).

My research approach involved exploring this case using more flexible and interactive style of elicits questions categorized with each response for analysis. The analytical objectives included their description and explanation of their relationship to each interviewee and group norms where applicable. The study design was applied to the

order of questions as well as additions, exclusions, or choice of particular questions derived from my interviews, data collected, and company websites reviewed (Muskat et al., 2012). In contrast, the selection of study design includes consistency in the approach when developing interview questions, data collection, and analysis with the approach taken (Lewis, 2015). Likewise, the consideration for a single-case versus a multicase study was part of the planning as well as its design congruence (Barlow, Hersen, Barlow, Nock, & Hersen, 2009). The information was then incorporated into the analysis and the reflection phase of this study.

Method

Qualitative approaches to information gathering involve direct interaction with individuals in a one-on-one or group setting. The purpose of the research was to find the answers to important questions (Marshall, 2010). By researching, it provided me the opportunity to understand experts' perspectives of the AED U.S. market, target markets, and awareness of emerging markets and product technologies. These qualitative data, gathered through the interviews, help me to address the specific business problem through a case study of multiple medical device manufacturers. The interviews included open-ended questions aimed at uncovering what strategies and potential strategies medical device manufacturing company marketing leaders, AED distribution channel leaders, and healthcare professionals using to expand their AED customer base in the consumer space. Interviews helped me to gather data to understand what strategies these leaders are using and what potential strategies may develop.

Research Design

The research design of this study was a case study. The case study was the most appropriate for this study allowing for detailed exploration of more current information within relevant subject matters while using multiple data collection and analysis processes (Yin, 2013). Yin (2013) underscored the choice of selecting a multiple or a multicase study for exploration as a choice for the researcher. I explored the strategies marketing leaders from a medical device manufacturer are using to develop their customer base, or not using, and emerging technologies in the AED consumer goods market.

I used multiple sources of data collection such as semi-structured interview questions and documentation thereby making the case study most suited for this research. Both the qualitative study and its design method contributed to the resolution of the business problem. Each question provided opportunities to describe the experiences and perceptions of the medical device manufacturer marketing leaders, distributors, and healthcare professionals on the topic of open business models (Chesbrough, 2012).

Reaching data saturation occurred after having leveraged the three types of data collection to the point at which there was a diminishing return in collecting more data (Marshall et al., 2013). These types include interviewing, assessing collected data, and reviewing the companies' website material. While collecting the data, I ensured there were the necessary quantity and quality as part of reaching saturation.

Population and Sampling

In choosing participants, I used a purposeful sampling approach. Participants of choice were from marketing management as well as change agents with decision-making responsibility and influence in their respective company. Participants of choice have influence with company steering committees and vision-sharing in strategic direction. This choice of sampling was in accord with Reybold et al. These authors depicted purposive sampling as the strategy of achieving the best fit data to answer the research question, making the best use of resources, and completing the study with resources available (Reybold et al., 2012). In purposive sampling, the participants selected had information that was relevant to the study (Petty, Thomson, & Stew, 2012).

A critical fundamental of creating credible research was obtaining an adequate sample (Marshall et al., 2013). To reach data saturation with a minimum of six participants by performing interviews with the respective participants, selecting a sample size was contingent on the need to reach data saturation. Saturation is the point at which diminishing returns in collecting more data exists (Marshall et al., 2013). Because the number of participants in this study was sufficient, reaching saturation was foreseeable. Their intellectual knowledge, decision-making responsibility, and access to resources allocation included important information which added value to this study.

I conducted the interviews by telephone with the option of audio recording when permissible. In the interview process, I targeted marketing leaders who were responsible for the U.S. market in the consumer and distribution groups. These marketing leaders

were from senior management ranks as well as change agents with decision-making responsibility and influence in their respective company. The preferences in participants were those who are responsible for strategic planning and marketing of the AED consumer goods product line.

The participants interviewed were the most eligible interview candidates to engage in my study and had the decision-making authority in infusing a new business model and influence change in marketing strategies. In the regards to the medical device and AED manufacturers operating in the United States, I formally approached (see Appendix A as sample letter of cooperation) all three which included Pseudo AED U.S, Pseudo2 AED U.S., and Pseudo3 AED U.S. I also approached Pseudo AED Distributor U.S and Pseudo AED Distributor2 U.S because of their unique distribution models. Because of their market presence and focus on health consumer products, the inclination was towards Pseudo AED U.S. (Noel & Van Groningen, 2014). These manufacturers engage in healthcare products and medical device manufacturing, specific to AEDs with proprietary business models and research and development (R&D) groups. I found more success with AED manufacturers distributors willing to share detailed information, to some degree, than from medical device manufacturers. In contrast, both medical device and AED manufacturers would not relate emerging market information in the consumer space, nor were there any contingencies on the willingness of participants to share it. To ensure all participants provide available data, I chose companies with public information available.

A point of saturation was achieved by performing interviews with a minimum of six participants from their respective companies and area of responsibility, coupled with sources of data from the company website and interviews. The point of achievement was reached whereby there were no new information or topics, contributing to reaching a point of saturation (Marshall et al., 2013). I conducted the interviews by way of conference calls to ensure depth of research by checking in with all participants to validate their responses.

Respecting participants' time, I conducted telephone interviews with brevity and efficiency, anticipating no longer than an hour in uninterrupted chambers. These accommodations are important as they are leaders and an important stakeholder in the company (Harvey, 2011). Jacob and Furgerson (2012) recommended that participants conduct interviews in a quiet and private location. The purpose was to minimize distractions, allowing for clear and audible communication, and to ensure data confidentiality during data collection. I reviewed the protocol and consent form process with participants to ensure compliance and sustainability throughout the fact-finding process.

Ethical Research

Research ethics is the interaction between researchers and the participants they study. The professional aspect of research ethics involves the issues of researchers' interactions with participants. Research ethics includes intellectual property, mentoring relationships, any potential fabrication of data, as well as plagiarism. As a researcher, I was under the obligation to demonstrate trustworthiness and credibility as I execute the

methodologies used in this research. This demonstration provided an ideal opportunity to employ ethical literacy as I engaged in these contemporary methods (Jackson, 2013).

Because this study specifically involves human participants, I made certain to include participants' protection documents, consent forms, and a letter of cooperation. Participants' names and contact information are not recorded in the research records. Participants' names and information gathered from the interviews remain confidential. Maintaining ethical conduct was imperative, especially while conducting research to protect the rights of human participants. Once in receipt of approval from the manufacturer, distributor, and healthcare professionals, I proceeded with the interviews because I expected to eliminate any foreseeable conflict of interest. The research procedures did not reveal criminal activity or child/elder abuse that necessitates reporting. The research procedures did not reveal or create an acute psychological state that necessitates referral.

Participants signed a consent form before the interview. I obtained Walden University Institutional Review Board (IRB) approval for this study. The IRB approval ensured the ethical protection of human subjects (see Appendix B). The words within the consent form adhere to the U.S. Food and Drug Administration, Department of Human Services and Walden University standards. At the time, I performed these interviews, I followed the interview protocol (see Appendix C). I completed the National Institute of Health Human Research Protection training (see Appendix D). As part of the protocol, I provided each participant with a copy of the inform consent document. Securing

signatures and scheduling a discussion with each participant was part of the interview protocol.

I ensured there was ample time to answer any questions they had and explained the purpose and reason for the study as well as their rights to withdraw. The importance of reviewing procedure and protocol is to affirm and underscore the confidentiality and voluntary process. The role of the IRB is to ensure research proposals are meeting the criteria of applicable law for acceptability, institutional regulations, and professional conducts and practices standards (Jackson, 2013). I actively anticipated and addressed each ethical dilemma occurring at every phase of the research. I also respected vulnerable populations and avoid putting participants at risk (DuBois et al., 2012). I did not interview participants who may have been members of a vulnerable population. I supported every decision with a scholarly peer-reviewed or a seminal source.

Last, I am maintaining the data in a safe place for 5 years after the date of the published date to protect the confidentiality of participants. As part of compliance and incentives, I will provide the senior management and participants a final copy of my findings. I am protecting the names of individuals and organizations by pseudonyms, to keep the participants and organizations confidential. This information is part of the consent statement and nondisclosure agreement.

Data Collection

Instruments

In the data collection process, I ensured the study sustained a qualitative interpretive research and the basic framework in collecting data and analyzed. The prior

research did not provide a framework for this study because it is in the public and business sector and not in the consumer space. The lack of a framework created a need to add to the research, seek new data, and instruments. The researcher is the main instrument of data collection in qualitative research (Bansal & Corley, 2011) contributing valuable information used for validation and proof.

I used open-ended questions to allow the participant to expand or emerge on the subject matter or phenomenon in question. I used semistructured interviews with leaders of the medical device manufacturer with questions regarding their marketing strategies and emerging technologies to expand their consumer goods customer base. Congruent with this approach, I sustained my role as the researcher by effectively interviewing each participant gaining clarity and consistency with each question; assessing collected organized and coded data, and reviewing the manufacturer's web material for any variance between data collected and data published. During the data collection process, I validated the necessary quantity and quality in each area of research as part of reaching saturation.

To gain profound experiences or views on a subject matter in this qualitative study, I followed Silverman (2013), and relied on interviews to gain as much detail as possible. In the initial permission letter to the medical device manufacturer, distributors, and healthcare professionals, I requested permission to initiate contact to introduce myself as the researcher and establish the premise of my study. Once the institutional review board (IRB) approved my proposal, a letter of cooperation to the participating companies followed, requesting permission to begin the interview process. The

information about the instrument that I planned to use was conveyed, pertaining to demographics and how it would remain congruent with other instruments used in previous studies. I overcame the disadvantage of being on the participants' premise face-to-face by utilizing telephone calls and audio recording capabilities when allowed (Pickard, 2012).

As the researcher, I continuously uncovered any relevancy between the analysis and data collection and data analysis guides in data collection (Buckle, Dwyer, & Jackson, 2010). The three levels of analysis included the presentation of the data without interpretation and abstraction. The second inclusion was a descriptive narrative using field notes, interview transcripts, and researcher interpretations. The third inclusion was building a theory based on interpretations and abstractions. Coding was a part of the data collection process for data taken from field notes and interview transcripts. By coding the data, I fractured the data and grouped it into codes for categorizing confluent events, statements, and identifying the data (Holton, 2013). The research procedures and the analysis/write-up plans were performed based on the data coding and not on the raw data containing any participants' identity. I develop a theory to explain what will happen to the data. To determine what will happen to the data, a series of questions were used to form the theory. They will be:

1. What phenomena do these data represent?
2. What category does a given incident indicate?
3. What is happening in the data, beyond the surface-level explanation?

I, as the researcher, used open coding to determine the theoretical sensitivity, transcend descriptive details, and encouraged a focus on patterns among incidents yielding codes.

I took several steps to ensure reliability and validity of data collected from the interview process by quickly transcribing the interview recordings and ensured accurate interpretation of the responses from participants (Yu, 2012). Upon completion of the interview and the interpretation of their response, I allowed the participants to verify the accuracy of the transcript through both telephone conversation and email allowing up to 10 days to review and return, as described in Seidman (2012). Participants reviewed their respective transcripts and verified that the transcriptions were correct. There were no discrepancies noted and secured an agreement with all participants ensuring that the research accurately interpreted his/her intended response for each question. Documentation was an important source of case study evidence from this research. I conducted a review of any documents on the study topic such as reports or studies. I retrieved information from the company's website regarding AED products, services, education & resources, specialties, marketing initiatives, financial posture, and innovation paradigms. I also retrieved information from FDA websites related to compliance and regulatory policies of AEDs, as well from a medical journal, and medical organizations and other governmental websites to reach triangulation. The responses across participants and corroborated data from the document review process were part of facilitating the convergence of data (Yin, 2014).

Data Collection Technique

The interview protocol included information, guidelines, and prompts to assist with executing the interview from start to completion and to assist with maintaining consistency across interviews (Jacob & Furgerson, 2012). I followed the procedures outlined in the interview protocol to conduct the interviews. The interview script had an introductory script. The script included the consent process which allows participants to ask questions. Because I was aware of the AED manufacturers' involvement of their requirement to respond to the FDA's PMA enforcement, there was an inclination with these companies to conduct all interviews by telephone only. The purpose of the interviews was to ensure accuracy and quality of each response to the research questions. As the researcher, I made it my responsibility to secure and document the answers to the questions and verbal responses. I used the following interview techniques to ensure the interview process is effective in fully engaging participants. Jacob and Furgerson (2012) recommended that researchers limit note taking during interviews so as not to distract from maintaining eye contact with the participant. I requested permission to record interviews to minimize the need to take notes.

Regarding the interviews, I requested from all participants to conduct the interviews in a quiet location (Jacob & Furgerson, 2012) and thus, all resulted at their business office. In making this request, it helped to eliminate distractions while ensuring privacy and confidentiality of the data collected. Documented interviews and meetings related to the topic provided an additional opportunity.

Advantages associated with using interviews recordings, as a source of data collection, was included as an option to participants when permissible by management and participant. This option allows researchers to capture data not previously recorded (Yin, 2014). The advantages also provided me an opportunity to listen to participants (see Doody & Noona, 2013). Audio recordings allow the researcher to replay the interview to capture details (Yin, 2014). Telephone interviews eliminated traveling and demands for more time to reach participants as well as adding travel expenses. Six telephone interviews were conducted each by telephone with no on-location interviews

In these remote access interviews by a telephone call, I secured prior approval from participants to record the interviews as indicated in the consent form. Each participant provided a signed consent form before his or her interview by email (see Doody & Noona, 2013). If the participant did not provide approval to having the interview recorded, I did not use audio recorders and only took notes.

Skype works over the Internet. My safety net for a possible weak connection was to use other devices and telecommunication transports. This alternative was a good prevention plan in avoiding disruptions to the interview process (see Hanna, 2012).

A poor interview was experienced with one of the AED distributors, however, it was mostly due to an overcommitment of time by the marketing leader. Although agreeing to participate in the interview, the focus was more on the existing PMA response to the FDA at the headquarters, than on the interview. I concluded the interview and both agreed on reconvening later. This resulted in a portrayal of mutual respect for critical tasks and professionalism.

Internet connectivity may vary depending on various components and services because of telecommunications providers and equipment. Although Internet or telecommunications connectivity never failed during the interviews, rescheduling was always an option. Reviewing the manufacturer's website material was part of the research and assurance of the collection quantity and quality needed utilizing editing tools, notes, written questionnaires, and saturation.

Data Organization Techniques

During my research, I requested permission from the participating companies to record all conversations during the interviews using a digital voice recorder device. However, because of their concern for security, in most cases, I was not permitted. My plan, after each interview, was to have the recordings from my iPhone uploaded using iCloud technology to download on my computer system in a password-protected database. Additional steps of precaution included backup to the cloud provider for safe keeping and identifying the recordings using labels to protect the identities of participants (Fernando, Loke, & Rahayu, 2013). The systems used for keeping track of data included a recording of teleconferencing; digital and hard copy transcribed notes; and answers to the structured questions, as well as information from manufacturer's website.

Regarding maintaining records and chronology, all documents such as schedules, logs, journals, and labeling systems are being kept within the database. I secured all consent forms containing participants' interviews and any other research material in the protection of any privacy risks. Maintaining data in a bank lockbox for a minimum of five years after the date of the published date will be my protocol to ensure compliance

and safekeeping for this study. After 5 years, the data will be destroyed by contracting a security company to protect the privacy of consumer information and reduce the risk of fraud and identity theft. I have taken appropriate measures to dispose of sensitive information derived from participant interviews and any other information, through such a company.

Data Analysis Technique

The data analysis technique included the review of the data without interpretation and abstraction. A descriptive narrative using field notes, interview, transcripts, and researcher interpretations was part of conducting an analysis of these interpretations and abstractions. To analyze these data gathered for analysis from these in-depth interviews, assessment of data collected, and company website, I used the modified van Kaam method (Van Kaam, 1959). My objective was to identify the themes from a purposive sample of a leading medical device manufacturer with approved consumer type AEDs by the Federal and Drug Administration (FDA). I used various applications, such as MS Word and Excel from the Microsoft Professional Suite software, to store the data collected in this study. I chose this application compared to NVivo and Atlas.ti software because of my familiarity with the use of the Microsoft Professional Suite and analytical attributes. Each decision supported with scholarly peer review references.

Yin's (2014) recommendation depicted the creation of a case study database in data collection as one to store the information collected. I stored all field notes, data collected from interviews, transcripts, and information from company official websites on a password-protected database on my computer in which I have sole access. I maintained

reliability and validity of the study (Yin, 2014) by rigorously following the protocol and process set forth by this study. Using a tree format of folders, I organized each by the participant with subfolders as supporting document to each interview as follows:

Folders

S 1-10

Sub-Folder

Inter1-6

Coding

X or O

Coding Levels

1-10 Positive or 0-(10) Negative

The database had a password protection feature and stored on the computer for 5 years. After 5 years, I will delete all raw data stored and collected from each of the files with the case study database. I will destroy all printed documents in the bank lockbox by shredding and discarding all documents using contracting a security company. As stakeholders of the company, participants are eligible to receive written results of the study. This is part of data organization and analysis protocol.

Confirmability and Replicability

Confirmability

In the quest to bring a unique perspective to this study, I confirmed and corroborate with other subject matter experts in the field. I accurately measured a qualitative study as past authors have enriched us with various potential concepts. I

documented the procedures for detailed inspection and checking of the data throughout the study. One method is confirmability defined by Petty, Thomson, and Stew (2012) as a paradigm shift from such methods of measures as reliability. Reliability defined by authors as Krefting (1991), focusing on the assessment of trustworthiness, confirmability validates the assessment and the findings reflect the focus of the inquiry. Venkatesh, Brown, and Bala, (2013) recommended the use of multiple sources to ensure reliability when conducting qualitative studies as well as one mixing qualitative with quantitative when considering participants and interview questions. Yin (2014) is consistent with Venkatesh, Brown, and Bala, (2013) because using multiple sources of data such as semistructured interviews and document reviewing also improves the reliability of a case study. Poortman and Schildkamp (2012) expand on the use of a tool to document systematic steps and procedures for data collection allowing consistency across interviews thus making the research reliable. Poortman and Schildkamp defined reliability as the measure of how replicable the research findings are independent of the researcher and instrument.

By implementing recommendations from previous authors to achieve reliability, various measures throughout the research process for this study and data collection did take place. By allowing participants to review the analysis summary of the study results based on my interpretation of the interview data (Yin, 2014) is further evidence of achieving reliability. Yin suggested using multiple sources of data such as semistructured interviews and document also reviewing improves the reliability of a case study. After

completing the study, I conducted a data audit to examine my data collection and analysis procedures and did not uncover any potential bias or distortion.

Replicability

Replicability, validity, and triangulation, per Golafshani (2003) as relevant research concepts, must be redefined to reflect the multiple ways of establishing the truth. Validity in research was this researcher's goal to ensure it was, in fact, the conclusion or derivative of the research reaching to the truth (Denzin & Giardina, 2012). Per Denzin and Giardina, subdividing validity into four types addresses a specific methodological question. I explored the methods and approach on how to investigate a research question while seeking validity. I researched for data triangulation and secured it, which is a technique that facilitates validation of data through cross verification from two or more sources (Myers, 2013). The purpose for using triangulation was for additional means to improve the credibility of the research findings. I achieved triangulation by interviewing, assessing collected data, and exploring company's website from the same corporation regarding the general and specific problem stated in this study. As part of the qualitative research for credibility, I described the participants' understanding of the subject matter to best describe it from their perspective. As in the interviews, I took the same approach while extracting information from PseudoAED U.S. manufacturers' websites, checking each response, and the transcript review to validate and triangulate the data.

Transition and Summary

In Section 2, I described the methodologies and strategies that I used to approach this study. The qualitative method of research, specifically a case design, has

demonstrated to be the best method to approaching this study. I described how conducting a qualitative research would yield the criteria of objectives and personal interaction needed to information and data collection. This qualitative information, through a multicase study with personal interviews, helped me to explore marketing strategies and business models related to consumer AED market in the United States. By exploring leaders perspectives in a leading medical device manufacturer, I uncovered their motivation, or the lack thereof, toward an open business model to grow their customer base.

Section 3: Application to Professional Practice and Implications for Change

In Section 3, I present my findings alongside implications for professional practice and social change. Section 3 includes my recommendation for reflections of all phases of the study and further study. The qualitative method, specifically a case design, was the method of approaching this study (Corbin & Strauss, 2014). Conducting qualitative research provided an opportunity for personal interaction needed during information and data collection. This qualitative information, through a multicase study with personal interviews, helped me to explore marketing strategies. These strategies included the relationship related to the consumer AED market in the United States. By interviewing psuedoAED leaders of the consumer goods division, AED distribution leaders, and healthcare professionals with the potential of motivating them toward an open business model, leaders may develop strategies for growth strategies in their customer base.

In this study, I addressed AED market potential in the United States. I explored some medical device manufacturing and distribution marketing leaders' marketing strategies to determine whether they are maximizing their customer base growth or leaving expansion opportunities in U.S. homes and public settings with unequipped AED programs. Given the facts on the consumer AED void and SCA statistics, further research of marketing strategies is recommended by this researcher. Further research is recommended to also explore the probability of influencing some AED manufacturing company leaders to recognize the value-add of an open business model, which stimulates innovation that may contribute to the prevention of SCD. Last, I recommend that AED

manufacturers and its distribution channels are made accountable in being responsive to answering questions that address why current methods of the prevention of SCD continue to fail.

Presentation of the Findings

In this section, I present the outcomes from the six interviews conducted. I provided the results from each of the questions presented to the participants. Each response is marked by an X for participants who responded to the respective question (Taylor, Bogdan, & DeVault, 2015), with a +1 to +3 agreement level where +3 is greatest agreement level and +1 being the lowest agreement level, as well as elaborated on the topic accordingly as illustrated in Appendix E. Participants who chose not to respond or disagreed with the question are marked 0 with a -1 to -3 disagreement level where -3 is the greatest disagreement level and -1 is the lowest disagreement level, and elaborated on the topic accordingly. I calculated an average score and noted it at the bottom of each question. Interpretation of the findings for each question is noted at the bottom of each table. A graph of the results for each question is provided to illustrate the results in visual form (see Appendix E).

Interpretation of Findings

The themes that emerged from the data collected are strategies, and yield professionals use while addressing the problem. The themes/strategies and supporting data included: strategic marketing information security, dealing with regulatory constraints, and commercial versus consumer focus.

Strategy 1: Strategic Marketing Information Security

A common concern for the security of strategic marketing was evident across the AED manufacturer participants with reluctance to discuss business models and marketing plans. During the interview and data collection, senior marketing leaders expressed their concerns regarding releasing any information. Strategic marketing information regarding the consumer market was an area AED manufacturers did not directly lead or influence and was left up to each individual distributor's business model. Scores in Appendix E illustrate low or negative O scores by AED manufacturer participants related to engaging in partnerships; receptive to open business models; and the topic of sharing marketing strategies with others in the industry. In contrast, participants from their distributor network scored high or positive X scores in the same topic area.

Strategy 2: Dealing with Regulatory Constraints

The United States FDA has limited the number of approved AED manufacturers making the available sample of participants limited. The U.S. market is one of the largest in the world while AED manufacturers are mostly founded and originally established overseas. Manufacturers, which are approved by the FDA, must comply with their regulations and undergo frequent compliance reviews such as submitting premarket approval applications (PMAs). These applications require AED manufacturers to undergo a more rigorous review than what was required to market the medical devices in the past. Per participants during the interviews, the FDA's reasoning for PMAs is to strengthened compliance reviews focused on the critical requirements needed to ensure the safety and reliability of AEDs and their necessary accessories. However, the effect of exacerbated

regulatory compliance, while important from a safety aspect, curtails AED manufacturers limiting their innovation and marketing strategies. The potential of new products for the consumer market in the distribution channels is directly correlated to federal and regulatory sanctions.

Strategy 3: Commercial vs. Consumer Market Focus

Another common theme noted from AED manufacturer participants was their delineation from the consumer as opposed to commercial product demands. During the research, participants were not familiar with this shift in the healthcare industry and its effects on the consumer or aging market. Consumer service and medical responsiveness are considered by the AED manufacturers as an aftermarket outcome, however, distributor partnerships and local community programs are effective. First responders and hospital emergency units rely on trained CPR and AED bystanders. AED Manufacturers have developed solutions in telemedicine but lack innovation in emerging markets being developed by their partner network.

AED manufacturers do not sell directly to consumers and rely on their distributor network for sales in this segment. This approach and perspective on the consumer market were shared by all AED manufacturers. In addition, AED manufacturers' close business models and fear of IP loss curtail any opportunity for innovation in the consumer space. AED distributors are more engaged with technology and innovative business development opportunities to expand sales and market growth while servicing consumer needs. Participants from healthcare services and systems providers of medicine agree that

even though they do not control or influence AED pricing, they would participate as a conduit to prescribing the need of an AED for a patient at risk for SCA.

Improving survival from SCA requires a system of care approach, and achieving Guidelines-level treatment for OOHCA requires significant effort across multiple healthcare segments. SCD prevention of healthy individual behaviors is not addressed in this study. AEDs are for the prevention of Sudden Cardia Death and do not prevent Sudden Cardiac Arrest. Participants from healthcare services and systems providers of medicine agree that comorbidities in the CVD population and the baby boomer increase in the elderly exceed sales growth of AEDs. Despite their agreement, sales in markets not supplying the demand and need of having an AED quickly accessible in the homes and public areas where the boomers spend their time, mortality statistics will continue to rise.

Participants from the manufacturing companies did not agree to comment in this area in the protection of their competitive marketing strategy or unfavorable to expand on their responses. Participants from distribution networks representing manufactured products agreed to comment and favorable towards an open business model which promoted innovation and new business opportunities. Participants from healthcare services and systems providers concurred that affiliations and partnerships were necessary when a knowledge, skillset, or resource is required and not possessed internally, to fulfill their business mission statement.

AED manufacturers support current publications showing evidence that there are limitations in having an AED at home. Affordability varies within the consumer market, yet boomers of less financial resources, look to insurance companies for support.

Consumers lack information and training in the use of an AED and thus uncertain in how or when to use it if they decide to own a home unit. In the home, AED monitoring solutions for prevention are emerging. Distributors are taking the initiative to create their own marketing strategies and look to their respective manufacturers to develop products that serve and accommodate the consumer market.

Participants from healthcare services and systems providers concurred that while it may be 15 to 20 years from having an AED in every home, they also agree that it is imperative for an AED to be readily accessible in every home. AED training and informing potential bystanders in the home is an area healthcare service and systems providers agree that it can be easily achieved. AED Bystander training programs lack in the total solution for an effective response to SCA and preventing SCD. This issue is left to First Responders and the distributor networks' business model of value-add solutions. Automated External Defibrillator distributors have adopted a new paradigm to address this market gap. AED Bystander training programs lack in the total solution for an effective response to SCA and preventing SCD. This issue is left to First Responders. Few AED distributors have adopted a new paradigm for address this market gap responders and the distributor networks' business model of value add solutions.

Only one of the two participating U.S. AED manufacturer is involved and approved to treat post-SCA patients using their medical devices and systems. The other U.S. AED manufacturer not involved in medical devices and systems supporting post-SCA hospital solutions was primarily because of technology development cost and

stringent regulation by the FDA. Complete recovery for SCA victims includes post SCA treatment by medical devices and systems.

Conclusions

The diversity in skill sets within the participants provided quality data from which to draw objective conclusions. These participants represented the top three AED manufacturers in the United States, North America, and the world. Participants shared similar perspectives in their responses. When compared to the distributors representing their respective AED product line, their perspectives differed in marketing strategies and market growth potential. For example, some distributors are focused on direct sales by way of the Internet and partnerships. Other distributors have non-profit mission statements are engaged in the direct delivery of the end-user as well as AED bystander training. When compared with the leaders in the medical community, their perspective on the AED manufacturers and distributors widely differ and question their direction away from the consumer demand and need.

The first conclusion with the AED manufacturer interviewees was their reluctance to engage in an open business model discussion. Their lack or limited response regarding this topic is primarily due to a business culture of protecting their intellectual property (IP) and fear of their information getting to competitors. Other reasons included their current compliance engagement from the U.S. Food and Drug Administration knows as premarket approval application (PMA), which was set forth in 2015. The regulatory challenge they face is FDA's 2015 initiative (USFDA, 2015) for the approval of their compliance stipulated for AEDs.

The PMA initiative is concerned with the FDA's issue of a final order requiring AED manufacturers to submit premarket approval applications (PMAs). As participants of this rigorous review, all AED manufacturers in the United States are cautious about providing internal marketing strategies other than those published for public knowledge. Whatever the underlining reason may have been, it was evident that each AED manufacturer chose to limit the information and remain within their respective business models. The participant interviews, alongside the use of the questionnaire, invoked discussion as to why there are no concentrated strategies for the home AED unit where most of SCA incidents are occurring.

Another conclusion is that AED manufacturers marketing strategies are more focused on the commercial market and less on the consumer market, allowing their market penetration onto the larger commercial accounts to influence smaller consumer accounts. Their respective distributors have the autonomy to plan and execute on their own marketing and sales strategies. If respective distributors adhere to and follow the guidelines set forth in their distributors' agreement, AED manufacturers allow them to execute their individual marketing and sales plans. Since each distributor falls in a sales volume tier, manufacturers concentrate their own sales in the commercial space.

A conclusion is that AED manufacturers have no significant focus on a home AED solution and yet the one manufacturer of a home AED unit with FDA approval, in this sample of participants, has established a consumer division along with a large tiered distributor channel. However, other than their FDA-approved home AED unit for sale

through distributors, their product line, and marketing is more concentrated on home monitoring units for the elderly and home-bound markets.

Outcomes

Because the timing of the interviews, cooperating partners were involved in an FDA initiative strengthening its review to help improve the quality and reliability of the automated external defibrillator (USFDA, 2015). The outcome with AED manufacturers included limited access to strategic marketing management as well as being receptive in engaging themselves with this doctoral study. Time was limited and value-add to their involvement was questioned, respectively. Outcomes of their marketing strategies delineated from the consumer market, distributor network, and distributor network-only models engaging partnerships in innovation.

Unlike the AED manufacturers, AED distributors focused on the consumer market and were receptive to an open business model and partnerships. However, their marketing strategies and sales channels are ubiquitous in nature. Larger for-profit distributors' sales are via the Internet, while some non-profit distributed provide AEDs at no cost to the consumer, as well as a bystander and CPR training.

Leaders from the medical community engaged in various medical rendering capacities in the field of CVD and SCD question the validity and purpose behind AED manufacturers' marketing and sales strategies. Moreover, they question their lack of focus in markets where SCA occur the most and innovation would be best served. While they do understand the scrutiny in which the FDA governs their end products, they remain skeptical of the AED price tag per unit. Medical professional disagree with the

cost of the AED products despite the regulatory challenges they face with FDA's 2015 premarket approval application (PMA) initiative (USFDA, 2015). The PMA initiative has to do with the FDA's issue of a final order requiring AED manufacturers to submit premarket approval applications (PMAs). The application forces AED manufacturers to undergo a rigorous review. This review has far more rigor that has been required of the AED manufacturers before marketing these devices in the past. The initiative itself is questioned by the medical leaders of its real motive behind FDA's rigor.

Outcomes of practicing a close business model were evident within the medical device and AED manufacturers. None of the participants working for the leading U.S. companies manufacturing AEDs were transparent in discussing their plans for product development or emerging markets. Their partnerships did not include innovation or integration to their existing product lines.

Outcomes from the interviews with participants representing AED distributor channels did provide proof positive of engaging in partnership for product development and innovation. This was specifically evident with distributors in for-profit business models. However, many of the partnerships uncovered focused on further sales distribution and community-based initiatives. Distribution and sales to sub-distributors were identified, primarily in the retail arena among large pharmacy chain stores as well as Internet sales. None of the sub-distributors were engaged in solutions involving CPR or bystander training.

One large distributor and participant that was engaged as a non-profit company providing AEDs in school sports for young adults, did have both an open business model

and servicing its market with a total solution. The solution involved providing AEDs to high school sports programs ensuring the safety of young athletes during sports events. The athletic department included CPR and AED bystander training to all coaches and administrative personnel.

Outcomes for consideration of further study regarding medical practitioners' perspective on CVD, is a potential need. Participants from healthcare services and systems providers of medicine agree that comorbidities in the CVD population and the baby boomer increase in the elderly, and that they may be exceeding sales and growth of AED markets. However, research in the study and current statistics continue to provide proof that over 88% of all SCAs are occurring at home and other remote areas. Thus, the assumptions stated before research are consistent with the finding. The question of CVD outnumbering AEDs may be less valid than that of the number of AEDs lacking marketing sales strategies in the market segments of need.

The data collected and its findings were part of the conceptual framework for this study with the product life cycle (PLC) theory as a continuum. The four life stages of a PLC in which a product passes through were evident during data collection from the participants. The product introduction cycle, including development and design compliance, was and continues to be an area of accountability which only the AED manufacturer own. Product growth, from a development and marketing perspective, was and continues to be a shared cycle of accountability by both the AED manufacturer and their respective distributors. The maturity life cycle of the AED was evident from the distributor participants, during the data collection, as distributors resell the product down

in tiers as far as the retailer. The maturity of market, price, and technology. The AED product decline, which distinctively shares more market characteristics with other products in the same stage than with itself at a previous or later stage, occurs in the shelf life of the distributors and retailers. As a vital life-saving product, having a maximum shelf-life of five years, the AED declines in reliability and technology. During data collection, it was noted that while the product declined over time, pricing was held by each tier of the distributor.

As the AED product line was infused onto organizational marketing strategies, PLC did provide useful insight into competitive tactics, an alternate perspective on how to address issues of supply and demand. However, the variance in marketing strategies from the manufacturer to the tiered distributors, yield different outcome to the respective organizations. Since it is people which manage organizations, their influence and the decision-making culture they created come from their behaviors. These decision-making cultures and behaviors noted in the participants, during the interviews, influenced their marketing strategies.

The problem-solving process for medical device manufacturers in the United States was noted to have a dominant approach by its marketing leaders to PLC. However, once the AED product was sold to master distributors and in turn master distributors to sub-distributors, manufacturers lost their dominance with marketing strategies. This was a pivotal and important finding during the exploratory and interview phase of the data collection. As one manufacturing marketing leader stated, “we do not sell directly to our consumer and only to our distributors. What they decide regarding marketing is their

decision as long as they are compliant with the manufacturer-distributor agreement". In losing their dominance, manufacturers could not longer contribute to growing their consumer customer base. In terms of the consumer market and its need to be supplied with AEDs in critical segments, manufacturer marketing strategy dominance and influence was lost.

Other findings and potential connection to the literature review from the data collected were noted during the exploratory process. The first and foremost was the connection of the data collected in contrast with the business marketing management recommendations from scholars in this field. The delineation in marketing strategies between the manufacturers and its distributors clearly showed disconnect and loss of opportunities in the consumer space. In terms of the healthcare and retirement trends of the aging boomer with the specific dependency of accessibility and immediate medical attention in rural areas, the manufacturer did not entertain the topic nor were they concern for these trends. While distributors to some extent are selling ubiquitously across markets and servicing the boomer, they have no specific strategy towards the consumer segment of the market. The same results were found in emerging technologies, safety, governance and bystander training. During the data collection and interview process, one distributor described the AED and its consumer market as "a commodity with little chance of being purchased by homeowners, just look at all the publications." Despite scholarly review and widespread information on this topic along with the knowledge that 88% of SCAs happen at home and public areas, data collected illustrates that there is no immediate change in marketing strategies by AED manufacturers their respective distributors. The

most receptive participants to the open business model and collaborative conversation regarding innovative marketing strategies were the healthcare professionals.

In conclusion, while the PLC may augment open business models, manufacturers are losing their dominance through both, PLC shortcomings, close business models, and marketing strategies in the consumer space. Additional losses include the curtailment of outside ideas and technologies to be infused and propagate onto their products and services. This lack of infusion has reduced AED manufacturers' their economic potential (Chesbrough, 2012), curtailment in their business growth and social responsibilities.

Applications to Professional Practice

The purpose of this multicase study was to explore the marketing strategies medical device manufacturing company leaders use to expand their consumer customer base. The results were inconsistent with the initial purpose. However until initial contact was made with the marketing manufacturers' leaders, it would have been impossible to uncover at an earlier stage. Medical device manufacturing company leaders were reluctant to discuss their marketing strategies in detail and pivoted strategic marketing for their consumer products to their distributor network. Their marketing strategies are to focus on commercial products serving the demand of their larger customer base and building their brand. Thus their strategy in label branding and product sales of medical devices will proliferate onto their consumer product sales, such as the AED, through their distributor network.

Making a shift towards the distributor network and healthcare professionals accommodated the study since focus remained in the consumer space. Although the

distributor network and healthcare entrepreneurs contributed to the study, it was also evident their strategic solutions specific to the home AED unit sales included a different strategic paradigm. Their paradigm included turnkey solutions for telemedicine; emergency responds systems, as well as the prevention of sudden cardiac death. Therefore, lobbying for regulation to expand their products to the home and public segments of the market, which remain without an AED, should be a consideration for action.

Based on peer-reviewed literature and SCD statistics from the AHA, distributors' partnerships should include organization focused on solving for boomer demand and healthcare solutions for the prevention of SCD by integrating their ideas and technologies. Healthcare entrepreneurs should be a challenge in launching for-profit and non-profit corporations with the mission to prevent SCD. These corporations would have the required strategic vision, robust resource, and limited regulatory requirements to invoke their solutions in the U.S. markets and beyond. The dissemination of these results would ensure the aging population of boomers' protection and prevention of SCD worldwide. Also Based on participant's comments from the AED manufacturer regarding their marketing only on the commercial and not on the consumer market, it is clear that marketing leaders need to re-think their marketing strategies.

The results of this study will be beneficial if these proposed applications for business practice, in the consumer market space with an emphasis on the boomer, are considered as critical objectives for more effective outcomes in regard to product affordability; home AED target marketing; decrease in healthcare expense; and reduction

of SCDs. In addition, by disseminating the findings and recommendations of this study through publications and presentation of its results in professional conferences, legislative session, and professional workshops, they will also yield effective outcomes. The entire study will be published in the ProQuest/UMI dissertation database. As the researcher, I also plan to publish parts of the study in several scholarly articles for other aspiring entrepreneurs to further the study.

Implications for Social Change

As part of social change, the procurement and placement of AEDs may prevent the loss of the lives to some of the 350,000 SCA victims dying annually of which 88%, or more than 308,000, are occurring at home and public settings (AHA, 2013). This qualitative case study and its design contributed toward a proposed solution for the business problem. Residual outcomes included opportunities to make an additional positive social change.

The outcomes derived from this research contributed to further motivate medical device manufacturing and distribution marketing leaders to infuse positive changes. Some changes may include influencing AED manufacturers, distributors, and medical entities to adopt an open business model to further increase revenue in sales and service; augment retail partners; infuse innovation in distribution channels, and gain a competitive edge in the consumer goods space. Residual outcomes for social change may contribute to improving the quality of life for the aging population while reducing the loss of the lives of 350,000 SCA victims dying annually (AHA, 2013). In reducing the loss of lives, it may help reduce costs of approximately $100 billion in annual expense (Heidenreich et

al., 2011) for the United States alone. The purpose was to explore their ability to contribute to the development of a new customer base in the AED marketplace. By exploring their plans for expanding public, consumer, and private accessibility, an expectation of remodeling their business remains as part of a contribution to social change.

Previous studies in this space, such as Pruchno (2012) and Rashidi & Mihailidis (2011), have not included the aging population entering retirement as an emerging market. Although the foundation is established in which to develop marketing strategies, no content is found on the topic. Yet, the large number of aging baby boomers retiring and moving to remote areas without in-home AEDs is the greatest gaps in the consumer market (Heidenreich et al., 2011). The literature review for this study premises other issues and potential marketing opportunities that are part of this review. The inclusion is specific to the dependency of accessibility and immediate medical attention and its relation to AEDs with the knowledge that 88% of SCAs happen at home and public areas. Solving for this dilemma would save the lives of the boomers; improve the changes of quality of life for survivors, and reduce healthcare cost in the hundreds of millions of dollars.

Recommendations for Action

Because of the findings stated in this study, I have several recommendations for action. The recommendations are stated below in the order of priority. Each recommendation includes specific and useful actions, as well as the identification of those entities needing to act.

Manufacturer marketing managers were the most difficult and least willing to cooperate with this study. Their reluctance included concerns in disavowing critical product and marketing information, which could be passed on to their competitors or regulators. This mindset was also prevalent and noted during any discussion or questions regarding the open business model. Their response pivoted to their distributor network as the entity of choice for this topic.

Other reluctance to collaborate and give their time included a need for a returned on investment for their contribution of information and time. Despite the fact, they work in a highly-regulated sector with the medical device manufacturing community, resolving serious product development and social issues, collaboration, and transparency will yield a space of innovation and marketing opportunity. Thus, my recommendation is to overcome AED manufacturers' close business models by way of lobbying for regulation to expand their products to the home and public segments of the market that remain without an AED. The dissemination of these results would ensure the aging population of boomers' protection and prevention of SCD.

AED Distributor marketing managers were the most receptive to an open business model and recipients of its value-add to their market growth. Distributors' business models varied with two distinct attributes and market focus. The first were those engaged in commodity and retail sales with the available product online or on the shelf where the market demand is filled by an as needed basis. This model has no proactive marketing and advertising model reaching the aging and boomer population nor homeowner. It has

no foundation for a proactive and preventive marketing strategy towards market growth and prevention of SCD.

For this type of distributor, my recommendation is for them to invest in marketing and advertising campaigns reaching the said market segment. In addition, I recommended that their partnerships include organization focused on solving for boomer demand and healthcare solutions for the prevention of SCD. The dissemination of these results would ensure the aging population of boomers' protection and prevention of SCD. The second type of distributor is classified as an integrator.

The integrator-type distributor is one engaged with an innovative approach to a complete solution. Their attributes include an open business model where both technologies in product development and marketing strategy solve the business problem and meet its social responsibility. While having both business model and attributes, which yield an opportunity for solutions development for the home and public areas, their focus is on the commercial segment of the market versus the consumer space. My recommendation is to develop strategies to solve for these market growth opportunities and move ahead of any potential future legislature mandating solutions by way of compliance. The dissemination of these results and proactive marketing strategies would ensure the aging population of boomers' protection and prevention of SCD.

Healthcare professionals and the corporations they represented during the study were the most engaged and partaking in solution development with the objective of saving lives. Their approach to SCD included global ubiquity and problem solving for each respective international market and inclusive of the aging population and its

vulnerability of CVD. However, their limitations and ability to solve for the prevention of SCD are contingent on the manufacturers and distributors of medical devices such as the AED. Since this research has uncovered that healthcare professionals participating and cooperating with this study have the financial resources and attributes of entrepreneurship, my recommendation would be to challenge them in launching for-profit and non-profit corporations with the mission to prevent SCD. These corporations would have the required strategic vision, robust resources, and limited regulatory requirements to invoke their solutions in the U.S. markets and beyond. The dissemination of these results would ensure the aging population of boomers' protection and prevention of SCD worldwide.

Recommendations for Further Study

The uniqueness of this study is that I addressed a business problem by way of new marketing strategies solving for market grown while directly contributing to a social issue that remains to be solved. Despite having the tools and resources to combat SCD, the United States is limited only by its entrepreneurial foresight and regulatory constraints. Future studies could explore a close examination of the strategies needed in lobbying regulatory entities to mandate for all new housing, existing homes, and public places to have an AED unit installed.

Further research in new AED technologies that reduce the cost of AED home units would contribute to the easing of access to a safe, reliable, and affordable product for the aging boomer and general population. Other recommendations of further studies include search-and-find mobile applications to locate AED positioning for immediate

access, as well as bystanders training during SCA in public areas. A larger sample and on-site interviews with medical device marketing managers would provide a greater opportunity to discuss the infusion of open business models and strategic partnerships. Future studies could include objectives towards social contribution in saving the lives of the more than 340,000 annual cases of SCD (AHA 2013) outside healthcare facilities. Inclusive in future studies, post-SCA medical equipment solutions to accelerate recovery and minimize loss of productivity at the workplace is highly recommended.

As it relates to marketing strategies, further studies should have specificity in researching how medical device manufacturers could pursue and compete in all AED markets by adopting an open business model. Furthermore, that studies include opportunities in establishing global presence while leading in technical reliability and quality by leveraging redundancy, intelligence, and automation with the highest operating standards possible. Lastly, the research should explore how an increase in profitability and cash flow could be leveraged in providing product affordability for the aging baby boomers.

Boomers will remain as the target market for medical devices such as the AED. However, boomers are living longer and working past age 65 which creates an opportunity for investments in products and services they will need upon retirement. Further study of the boomer and investment opportunities in products and services they will use or consume in the future are recommended. Boomers will continue to be an at-risk aging population with large healthcare facilities across remote and suburban areas back to the metropolitan and inner city areas to minimize expenses. Further studies on

how to solve the vast amount of healthcare services needed for the aging boomers retiring in remote areas with less emergency response services and resources are recommended.

Reflections

I conducted this qualitative, multicase study to explore participants' strategic thinking, business model paradigm, and forward-thinking marketing strategies. Moreover, I conducted the study to explore their experiences and perceptions on open business models and seeking external expertise for innovation and social contribution. The process exposed me to passionate and dynamic individuals dedicated to their mission and the fundamental factors motivating them to sustain market growth. I was very thankful for the exposure into this industry and impressed by the level of information sharing by participating distributors and healthcare professionals. Their passion for meeting the market demand and social needs epitomized a sincere accountability toward the prevention of SCD.

As the researcher, I had preconceived ideas that the cooperating manufacturing companies would be receptive the purpose of my research. However what I experienced was a cautious and distant reception, filled with potential risk in conveying intellectual property and marketing strategies. In the same way, I approached my cooperating companies with an assumption that they would recognize the potential value in the research process. The experience was a total antithesis and had to resort to leveraging their accountability and social responsibility to this initiative.

In contrast, the experience was considerably different with participants from the AED distribution network and healthcare professionals. They welcomed the value in

partnerships and collaborative engagement as a way for business growth and combating SCD. The effects of this researcher on the interface with participants throughout the interviews yield changes in my perspective toward the problem-solving paradigm of the study.

Summary and Study Conclusions

The study was conducted to solve a business problem. My initial perception was that by influencing medical device manufacturer marketing managers to infuse an open business model, the existing paradigm would be changed. The change was expected to contribute towards new marketing strategies focused on the growth of the consumer market. The true outcomes, after the research, were considerably different.

In this qualitative, multicase study, I used a questionnaire as the premise during the interviews with the participants. Thus, it provided considerable insight to AED manufacturer managers' mindset and marketing perspectives towards the commercial and consumer markets. The data collected, analyzed, and illustrated, supported the conclusion that marketing manufacturer marketing strategies do not extend to the consumer market as they are in the commercial market. Also, findings indicated that AED manufacturers do not sell directly to the consumer nor are they involved with or influence the marketing strategies for their distributors. Furthermore, findings supported the notion that their reluctance to engaging in any such study outside their silo is indicative of their close business model and protection of product knowledge and new developments. On the other spectrum of this paradigm are the distributors and healthcare entrepreneurs immersed in growth initiatives and emerging mhealth technologies. While neither have a

specific focus on the total home unit solution or the baby boomer market, they practice an open business model receptive to new ideas and partnerships.

Based on this study and previous research, I argue that a better business model, regulatory emphasis, and social responsibility, are needed for a better model to improve the reduction of sudden cardiac deaths. Therefore, this study demonstrates a need for further investigations on other factors that may possibly affect the development of new marketing strategies and regulatory mandates to improve AED performance, access, cost, and search-and-find technologies to grow the AED consumer market.

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Appendix A: Cervantes Letter of Cooperation Request

SUBJECT: Request of Pseudo AED U.S., Inc. for Arturo Cervantes Doctoral Study

1. This letter is to request approval to interview six marketing and sales professionals currently working for **Pseudo AED U.S., Inc.** as part of a doctoral study. The Title of the study is **Exploring Strategies for Expanding the U.S. Automated External Defibrillator Market.**

    a. Mr. Cervantes's doctoral study research design requires interviewing marketing and sales managers to obtain firsthand experience and knowledge related to marketing strategies medical device manufacturing company leaders use to expand their U.S. consumer customer base.

    b. Mr. Cervantes selected **Pseudo AED U.S., Inc.** because the company is identified you as an industry leader in the United States and North America. Interviewing members of **Pseudo AED U.S., Inc.** should enrich the results of his research.

    c. The questions of the interview do not intend to measure or evaluate the practices, procedures, or operations of **Pseudo AED U.S., Inc.**, its subordinate organizations, its corporate offices or affiliates.

    d. Granting permission to conduct the interviews is not an inference that **Pseudo AED U.S., Inc.** is either endorsing or sponsoring this study. Furthermore, **Pseudo AED U.S., Inc.** will not assume any liability for the research under this study.

2. The Principal Researcher for this study is Mr. Arturo Cervantes.

    a. Mr. Cervantes is a doctoral candidate in the school of Business and Technology at Walden University.

    b. Mr. Cervantes is the College President for Fortis College in Houston, Texas.

    c. Mr. Cervantes is currently working on a qualitative case study exploring strategies for expanding the U.S. Automated External Defibrillator Market with a social contribution in preventing sudden cardiac deaths (SCD) in the United States.

d. Mr. Cervantes' doctoral study intent is to identify and collect the most valued and relevant elements in the marketing, sales, and distribution of the AED to the consumer market.

e. Dr. Michael Ewald, of the Walden University's College of Management & Technology DBA Program, will be the contributing faculty supervising this research.

3. This is a request for cooperation to allow members of **Pseudo AED U.S., Inc.,** to engage in interviews to provide their perceived insight and knowledge.

    a. The participation in this interview is voluntary. Participants meeting the criteria and electing to participate in this interview not only will have the option to decline to participate without penalty; they will have the option to abandon the interview at any time during the interview process.

    b. There will be no incentives or rewards offered for participating in the interview.

    c. Mr. Cervantes designed the questions to gather the knowledge and experience of the participants on business performance and model, product distribution, product affordability, strategies for expanding consumer markets, and contribution to minimizing SCD.

    d. All data collected will be from public operations and execution processes related to the experience and knowledge of the participants.

    e. The interview will entail ten open-ended questions related to strategies in expanding the AED consumer market.

    f. Mr. Cervantes request interviewing the participants as means of verifying the responses to the interview questions.

    g. To verify Mr. Cervantes' interpretations of the interviews maintained the integrity of their responses and his inferences accurately express the participants' opinions, Mr. Cervantes may schedule a follow-up member-checking without any new questions with participants as a means of verifying information and validity only if needed.

    h. Mr. Cervantes will verify the accuracy of the transcript by allowing the participant to have the opportunity to amend, modify, expand, or clarify any of his or her original responses.

4. Mr. Cervantes will protect the rights and welfare of **Pseudo AED U.S. Inc.,** and its participants by applying the following provisions.

    a. Only Mr. Cervantes, and his doctoral committee (Dr. Michael Ewald, Dr. Kelly Chermack, and Dr. Judith Blando), and authorized Walden personnel will have access to the study's data.

    b. Mr. Cervantes will not use the participant responses outside the scope of his research.

    c. Mr. Cervantes will edit all responses to remove any information describing specific information about **Pseudo AED U.S., Inc.,** its subordinate units, its higher command, or information readers can use to identify the selected participants.

    d. Mr. Cervantes will code all participants' names, remove company name from marketing documentation, and perform all data analysis and conclusion based solely on this data code in order to protect the identity of the participants.

    e. Mr. Cervantes intends to conduct all interviews over the phone.

5. Mr. Cervantes does not have any influence or connections with **Pseudo AED U.S., Inc.,** or its employees eliminating potential conflict of interest concerns.

6. The point of contact is the undersigned.

Arturo Cervantes

Arturo Cervantes, MBA
DBA Candidate
Technology Entrepreneurship
College of Management & Technology
Walden University
Email: arturo.cervantes@waldenu.edu
Mobile: (210) 569-4134

_____

Pseudo AED Signee
Public Information Officer
Pseudo AED U.S., Inc.

Appendix B: Interview Protocol and Questions

Interviewee Name: _____

Interview No: _____ Date: _____

Introduction:

Before we begin the interview, I would like to take this time to discuss and explain the consent document before you. After explaining this document, I will be asking for your signature to indicate that you are willing to participate in the study and this interview.

Thank you for agreeing to this interview. (Go through the informed consent of the participant).

After obtaining signature:

As indicated in the inform consent document this interview will be recorded. (Start the tape recorder).

Interview Questions

1. Would you describe how your company's business model is open to partnerships that promote innovation?
2. How does the U.S. automated defibrillator market compare to others in the world?
3. How has your AED distributor network model evolved over the last few years?
4. How far are we from having an AED in every home?
5. How will first responder services be affected in case of SCA with hospitals moving from rural to metropolitan areas?
6. How is product affordability of AEDs for the aging senior consumer being addressed by your company?

7. Would you describe your company's perspective of AED Training Programs as a product value-add for market growth?
8. How have AED recalls influenced your product design?
9. Despite public awareness of CVD and large market share of AED sales in the United States, why does CVD still account for over 340,000 deaths outside of healthcare settings each year?
10. Would you elaborate on your company's involvement in medical device solutions for hospital treatment post-SCA?

Post Interview Comments:

Thank you for participating in this interview.

Appendix C: National Institutes of Health Training Certificate

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **ARTURO CERVANTES** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 12/27/2015

Certification Number: 1941111

Appendix D: Tables of Interpretation of Findings

Table D1

Strategies and Themes for S1

S1: How Open to Partnerships	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Are very open and innovation-centric with the potential to innovate yet protective of intellectual property (IP)	0-3	O-2	X+3	X+2	X+1	X+1
Lead with industry's technical knowledge by exploiting external resources for knowledge base	0-3	0-2	X+3	X+3	X+1	X+2
Need a paradigm change in capability to transform the business for new growth opportunities	0-3	0-2	X+3	0-1	X+1	0-1
Average Score	-3	-2	+3	+2	+1	+1

Interpretation of the findings:

- Interviewers from the manufacturing companies did not agree to comment in this area in protection of their competitive marketing strategy or unfavorable to expand on their responses
- Interviewers from distribution networks representing manufactured products agreed to comment and favorable towards an open business model which promoted innovation and new business opportunities
- Interviewers from healthcare services and systems providers concurred that affiliations and partnerships were necessary when a knowledge, skillset, or resource is required and not possessed internally, to fulfill their business mission statement

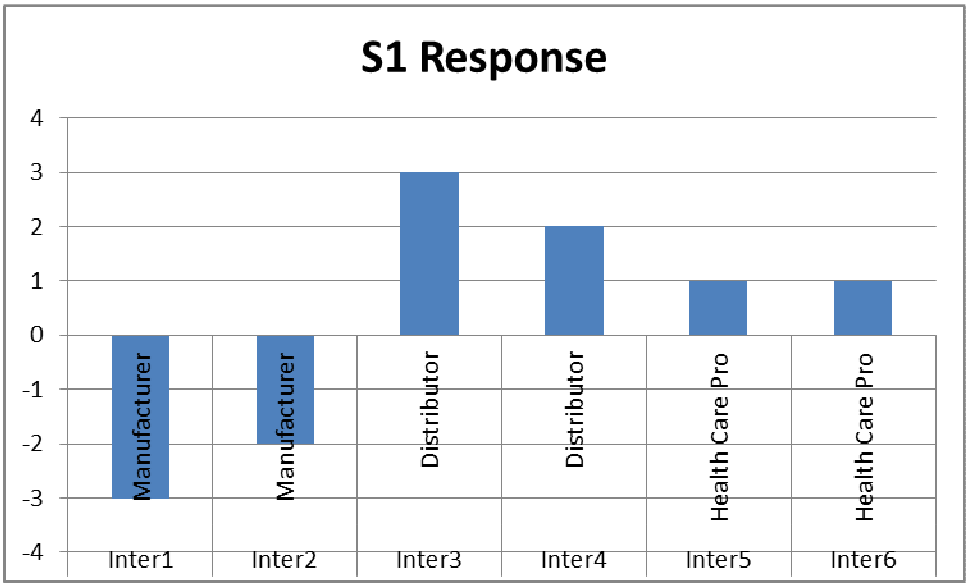

Figure D1. S1 response chart.

Table D2

Strategies and Themes for S2

S2: Defibrillator Market Comparison U.S. to World	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
U.S. to World dominance – FDA approved	X+3	X+2	X+1	X+1	0-1	X+2
Europe and Latin America next largest with growth potential	X+2	X+3	X+1	X+1	0-1	X+3
Asia and Pacific Realm smallest share with slow growth and concerns with IP breaches	X+1	X+1	0-1	0-1	0-1	X+1
Average Score	+3	+3	+1	+1	-1	+3

Interpretation of findings:

- The United States FDA has limited the number of approved AED manufacturers
- The U.S. market is one of the largest in the world while AED manufacturers' are mostly founded and originally established overseas
- The next largest market opportunity is with growth in Europe and Latin America, with Asia and the Pacific Realm following
- Manufacturers remain concern with losing intellectual property (IP) in entering the Asia and Pacific Realm markets

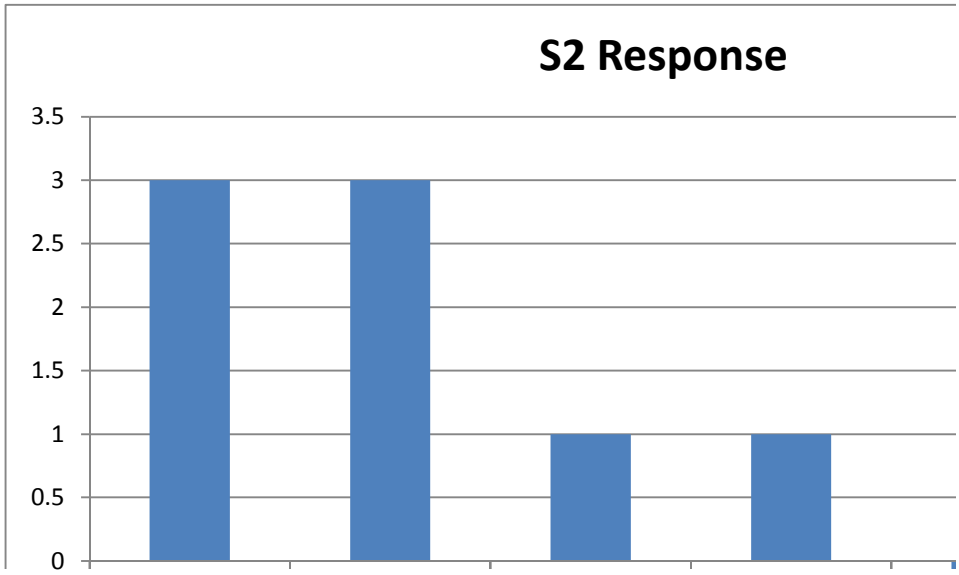

Figure D2. S2 response chart.

Table D3

Strategies and Themes for S3

S3: Evolution of the Distributor Network Model	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Commercial networks traditionally have included more corporate oversight with less oversight on consumer distributors and remain that way today	O-3	O-3	O-3	X+3	O-2	O-1
Traditional models applied to commercial networks and retail via Internet distributions are continuing to evolve within the distributor networks	O-1	O-3	O-3	X+3	O-2	O-2
General community use and First Responder use type products will remain with consumer distributors; Clinical use type products with corporate field sales force. No direct sales from manufacturers to consumer markets are expected in the future	X+2	X+3	O-3	X+3	X+2	X+1
Average Score	-2	-3	-3	+3	-2	-2

Interpretation of findings:

- The United States FDA has limited the number of approved AED manufacturers
- The U.S. market is one of the largest in the world while AED manufacturers are mostly founded and originally established overseas
- The next largest market opportunity is with growth in Europe and Latin America, with Asia and the Pacific Realm following
- Manufacturers remain concern with losing intellectual property (IP) in entering the Asia and Pacific Realm markets
- Product utilization by the consumer reluctance remains in purchasing decisions

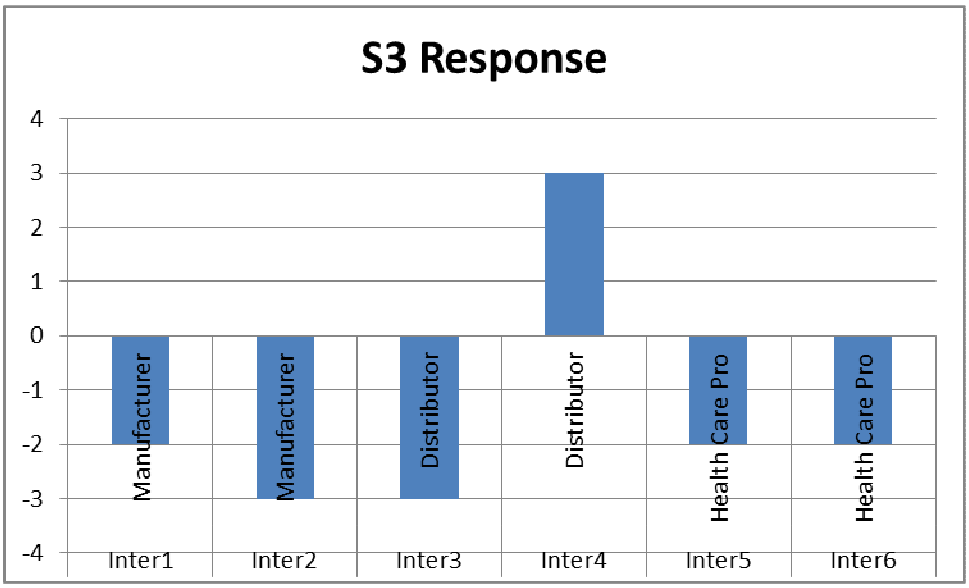

Figure D3. S3 response chart.

Table D4

Themes and Strategies for S4

S4: AED in every home forecast	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Consumer affordability and its use is volatile	O-2	O-3	X+2	X+1	X+3	X+3
Bystander reluctance of legal risks challenges in home and public areas of AED utilization	X+2	X+3	X+2	X+3	O-3	O-3
Home technology innovations in monitoring are emerging	X+2	X+3	X+2	X-1	X+3	X+3
Average Score	+2	+3	+2	+3	+3	+3
Interpretation of findings: • AED manufacturers support current publications showing evidence that there are limitations in having an AED at home • Affordability varies within the consumer market, yet boomers of less financial resources, look to insurance companies for support • Consumers lack information and training in the use of an AED and thus uncertain in how or when to use it if they decide to own a home unit • In-home AED monitoring solutions for prevention are emerging • Interviewers from healthcare services and systems providers concurred that while it may be 15 to 20 years from having an AED in every home, they also agree that it is imperative for an AED to be readily accessible in every home. AED training and informing potential bystanders in the home is an area healthcare service and systems providers agree that it can be easily achieved						

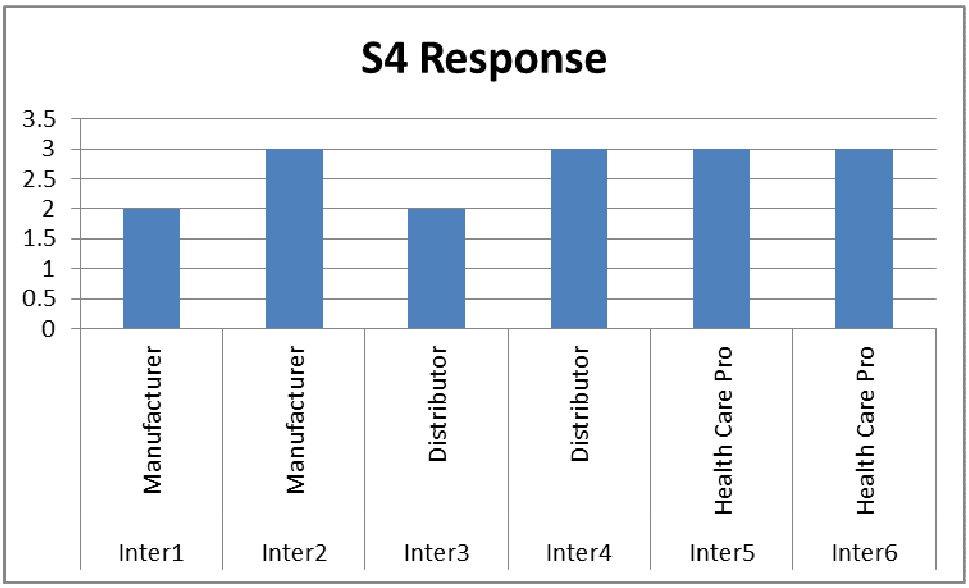

Figure D4. S4 response chart.

Table D5

Strategies and Themes for S5

S5: Responder services effects on SCA associated with hospitals rural-to-metropolitan area transition	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Consumer demands for product will be serviced in accord with market shifts	O-3	O-2	X+3	X+3	X+2	X+1
First Responder services will continue to grow and adapt to consumer demands	O-3	O-2	X+3	X+3	X+2	X+1
Home technology innovations in monitoring will grow with this market shift as boomers are located further from first-responder services	O-3	O-2	X+3	X+3	X+2	X+1
Average Score	-3	-2	+3	+3	+2	+1
Interpretation of findings: • AED manufacturers are not familiar with this shift in the healthcare industry and its effects on the consumer or aging market • Consumer service and medical responsiveness is considered by the AED manufacturers as an aftermarket outcome, however, distributor partnerships and local community programs are effective • First responders and hospital emergency units rely on trained CPR and AED bystanders • AED Manufacturers have developed solutions in telemedicine but lack innovation in emerging markets being developed by their partner network • Interviewers from healthcare services and systems providers concurred that the responders time will increase and that later arrival times will decrease the patient's chances of survival from SCA						

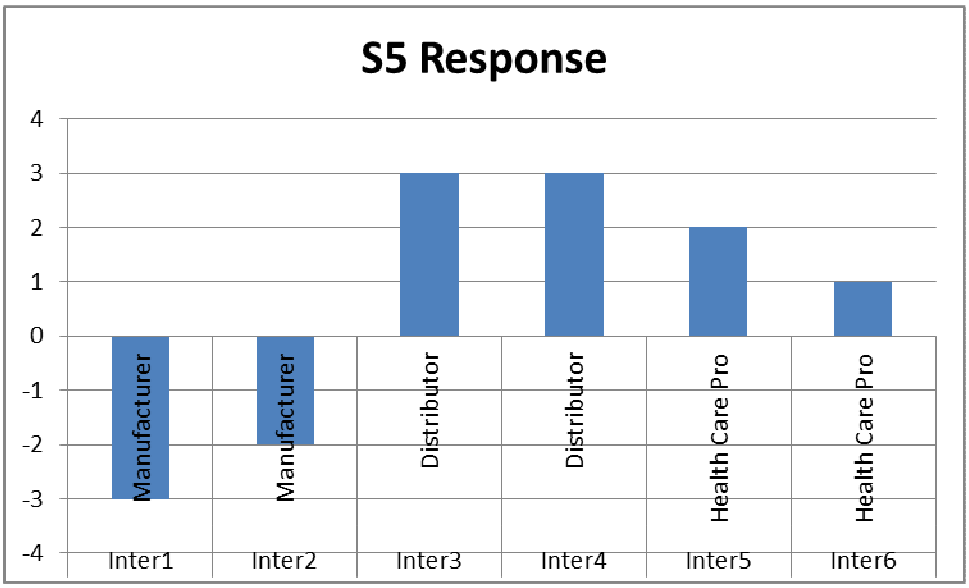

Figure 5D. S5 response chart.

Table D6

Strategies and Themes for S6

S6: Product affordability of AEDs for the aging senior consumer	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Consumer market is indicating price is too high and needs lowering trends	O-3	O-3	X+2	X+1	X+3	X+3
Innovation and new product releases will influence lower pricing on existing models with respect to all segments of the consumer market	O-1	O-1	X+3	X+2	X+3	X+3
Partnerships from distribution channels are adapting their business models to address consumer needs	X+1	X+2	X+2	X+3	O-3	O-3
Average Score	-3	-2	+2	+2	+3	+3
Interpretation of findings: • AED manufacturers do not sell directly to consumers and rely on their distributor network for sales in this segment • AED manufacturers' close business models and fear of IP loss curtail any opportunity for innovation in the consumer space • AED distributors are more engaged with technology and innovative business development opportunities to expand sales and market growth while servicing consumer needs • Interviewers from healthcare services and systems providers of medicine agree that despite the fact that they do not control or influence AED pricing, they would participate as a conduit to prescribing the need of an AED for a patient at risk for SCA						

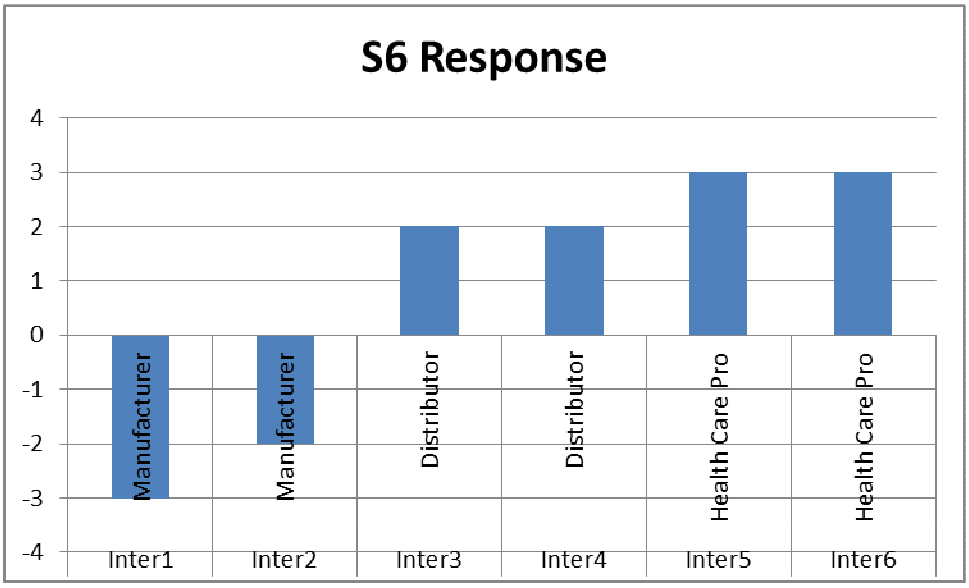

Figure D6. S6 response chart.

Table D7

Strategies and Themes for S7

S7: Describe your company's perspective of AED Training Programs as a product value-add for market growth	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
AED training solutions as a value add for AED manufacturer and its distributor network	O-3	O-2	X+3	O-2	X+1	X+2
Innovation and new product releases contribute to the ease of AED use reluctance	O-3	O-2	X+3	X+1	X+3	X+3
Partnerships from distribution channels are adapting their business models to address consumer needs	O-3	O-2	X+3	O-1	X+2	X+2
Average Score	-3	-2	+3	-2	+2	+2
Interpretation of findings: • AED Bystander training programs lack in the total solution for an effective response to SCA and preventing SCD • This issue is left to First Responders and the distributor networks' business model of value add solutions • Few AED distributors have adopted a new paradigm to address this market gap						

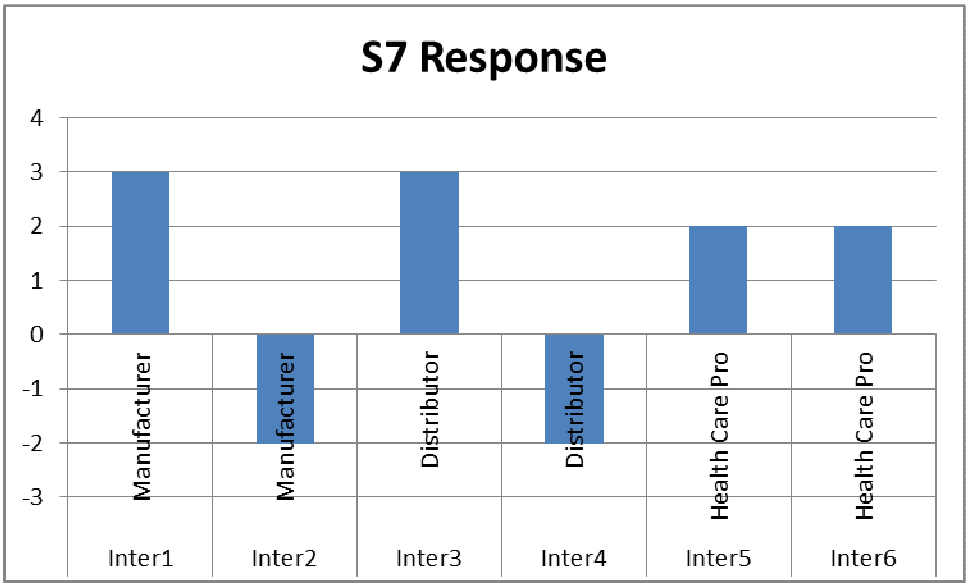

Figure D7. S7 response chart.

Table D8

Strategies and Themes for S8

S8: AED recalls influence on your product design	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
AEDs sold in the U.S. must be Class III approved	X+3	X+3	O-1	X+2	X+1	X+1
Products from 2012 to present have overcome past deficiencies in being unable to deliver needed defibrillator shock in a cardiac emergency situation, yet the FDA remains with rigorous enforcement of its policies and oversight through PMA	X+2	X+3	O-1	X+3	X+2	X+2
Manufacturer's self-initiate voluntary medical device recalls of its AEDs to ensure reliability and performance	X+2	X+3	O-1	X-3	O-1	O-1
Average Score	+2	+3	O-1	+2	+1	+1
Interpretation of findings: • AED Bystander training programs lack in the total solution for an effective response to SCA and preventing SCD • This issue is left to First Responders and the distributor networks' business model of value add solutions • Few AED distributors have adopted a new paradigm for address this market gap						

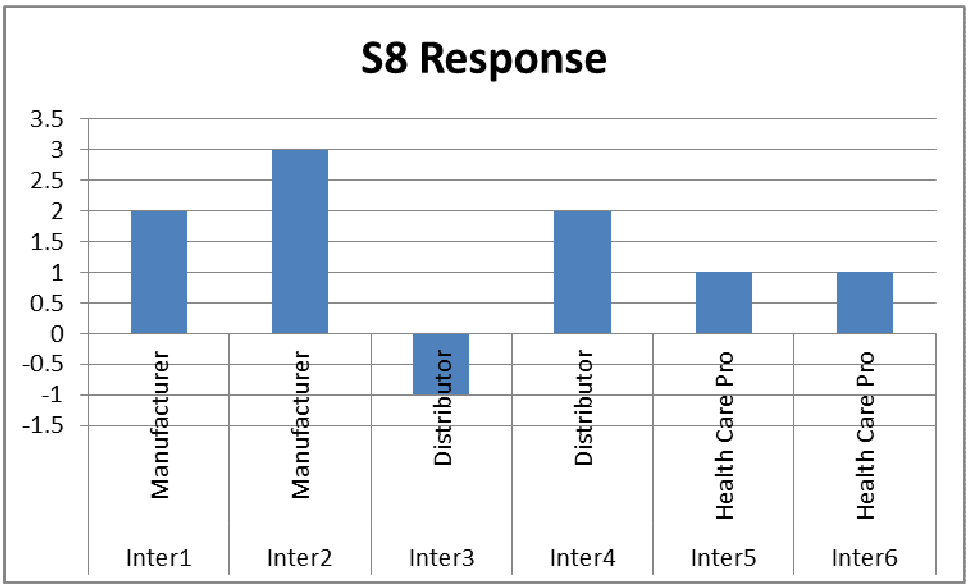

Figure D8. S8 response chart.

Table D9

Strategies and Themes for S9

S9: CVD still account for over 340,000 deaths in the United States outside of healthcare settings each year despite volume sales	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Heart disease remains prevalent in this country due to eating habits; lack of exercise; and tobacco smoking	X+1	X+2	X+1	X+1	X+3	X+3
Sudden Cardiac Arrest is both result of poor living behaviors and genetics	X+3	X+3	X+1	X+1	X+2	X+2
OOHCA Guidelines / System of Care obstacles exist	X+3	X+2	X+1	O-1	O-2	O-2
Average Score	+2	+2	+1	+1	+2	+2
Interpretation of findings: • Improving survival from SCA requires a system of care approach, and achieving Guidelines-level treatment for OOHCA requires significant effort across multiple healthcare segments • SCD prevention of healthy individual behaviors are not addressed in this study • AEDs are for the prevention of Sudden Cardia Death and do not prevent Sudden Cardiac Arrest • Interviewers from healthcare services and systems providers of medicine agree that comorbidities in the CVD population and the baby boomer increase in the elderly exceeds sales and growth of AEDs						

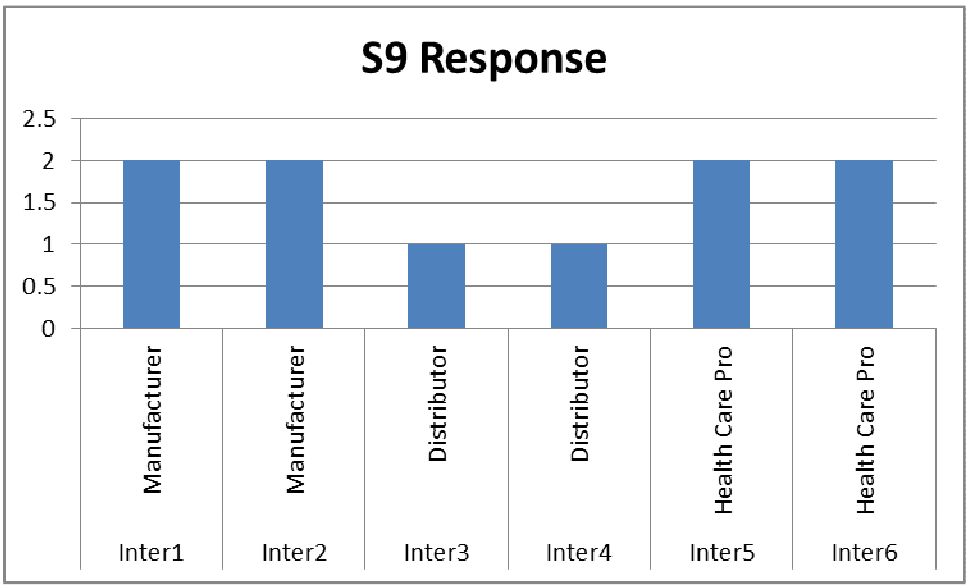

Figure D9. S9 response chart.

Table D10

Strategies and Themes for S10

S10: Role your company plays in medical device solutions for hospital treatment post-SCA	Inter1m	Inter2m	Inter3d	Inter4d	Inter5h	Inter6h
Ventricular fibrillation (a rapid quivering of the main pumping chambers in the bottom of the heart) called the ventricles occurring in SCA, is treated by other medical devices post-defibrillation	O-3	X+3	X+3	X+3	X+3	X+1
Past heart attacks leave scar tissue that changes the electrical patterns of the heart. This risk factor is treated by other medical devices manufactured by our company	O-3	X+1	O-3	O-3	O-2	O-2
Genetic disorders that cause subtle changes in the heart rhythm are medical treatment and surgically implanted versions for patients at high risk	O-3	X+2	O-3	O-3	O-3	O-1
Average Score	-3	+2	-3	-3	-2	-1
Interpretation of findings: • Only one U.S. AED manufacturer is involved and approved to treat post-SCA patients using their medical devices and systems • Less U.S. AED manufacturers are in the medical devices and systems supporting post-SCA hospital solutions • Complete recovery for SCA victims includes post SCA treatment by medical devices and systems						

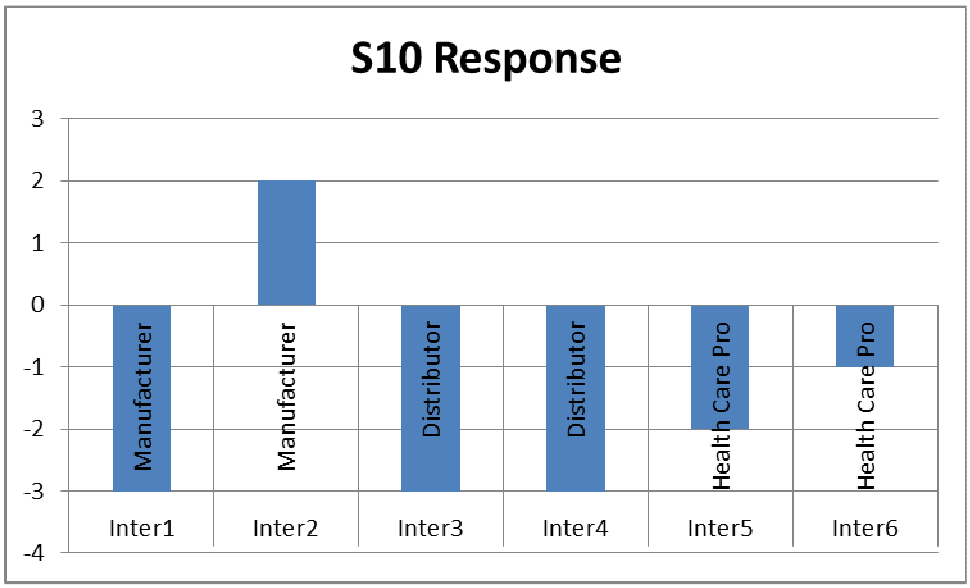

Figure D10. S10 response chart.