FUNDAÇÃO GETÚLIO VARGAS
ESCOLA DE ADMINISTRAÇÃO DE EMPRESAS DE SÃO PAULO

ANDRES LALINDE

NEED AND OPPORTUNITY: WHAT ARE THE MAIN THREATS TO THE PHARMACEUTICAL INDUSTRY IN LATIN AMERICA?

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Campo do Conhecimento: INTERNACIONALIZAÇÃO DE EMPRESAS

Orientador Prof. Dr. ANTONIO GELIS FILHO

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Profa. Dra. ANTONIO GELIS FILHO

_____
Prof. Dr. TALES ANDREASSI

_____
Prof. Dr. RICARDO RATNER ROCHMAN

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For my wife, whose unwavering support kept me going over several sleepless nights. For Domino, the best morale officer a man can have.

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Resumo

Os preços altos de produtos farmacêuticos patenteados sempre têm sido uma polêmica na América Latina. Considerando as disparidades económicas na região e a falta histórica do desenvolvimento, muitas vezes os preços altos servem como barreiras contra o acesso aos medicamentos essenciais. Por um lado, as companhias farmacêuticas dizem que os preços elevados são necessários para financiar os processos de pesquisa e desenvolvimento e para gerar um retorno do investimento lucrativo. Por outro lado, os consumidores, tanto privados como públicos, dizem que os preços altos têm resultado em uma falta histórica de medicamentos baratos. Neste debate, ambos lados têm realizado uma série de manobras e contramanobras que têm exposto algumas das vulnerabilidades do setor. Utilizando vários métodos de análise e entrevistas com profissionais no setor, este projeto analisa as vulnerabilidades do setor para determinar o risco, ao mesmo tempo tentando a responder à pergunta: Quais são as ameaças principais na segurança da indústria farmacêutica na América Latina? Justificação deste projeto é o aumento dos crimes relacionados aos produtos farmacêuticos na última década, que têm exposto os pacientes a um número de riscos mais alto. Uma compreensão das ameaças principais é necessária para melhor mitigar o risco, garantir a integridade de produtos e preservar a saúde pública.

Palavras-chave: Segurança, Ameaça, Farmacêuticos

Abstract

The high prices charged for patented pharmaceutical products have always been controversial in Latin America. Given the region's ongoing economic disparities and history of underdevelopment, high prices have often served as barriers to access for essential medicines. On one hand, pharmaceutical manufacturers argue that high prices are necessary to support continued research and development and to generate a profitable return on investment. On the other hand, consumers, both private and public, argue that high prices have resulted in a historic, unmet need for affordable treatment options. Over the course of this debate, both sides have conducted a series of maneuvers and counter-maneuvers that may have ultimately exposed some of the industry's vulnerabilities. Through a series of analysis tools and interviews with industry professionals, this project examines vulnerabilities to determine risk while simultaneously attempting to answer the question: What are the main security threats to the pharmaceutical industry in Latin America? Justification for this project stems from the sharp increase in pharmaceutical-related crimes over the past decade that, in turn, have exposed patients to a greater number of risks, such as the risks of counterfeit and diverted products. An understanding of the main security threats is necessary in order to best mitigate risk, ensure product integrity and preserve public health.

Key words: Security, Threat, Pharmaceuticals

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LIST OF ABREVIATIONS

ACTA – Anti-Counterfeiting Trade Agreement
API – Active Pharmaceutical Ingredient
ARV – Anti-Retro Viral
FTA – Free Trade Agreement
HIV/AIDS – Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IMPACT – International Medical Products Anti-Counterfeiting Taskforce
IP/IPR – Intellectual Property/International Property Rights
NGO – Non-Government Organization
OLP – Online Pharmacy
PESTEL – Political Economic Social Technical Environmental Legal
PSI – Pharmaceutical Security Institute
SWOT – Strengths Weaknesses Opportunities Threats
TRIPS – Trade Related Aspects of International Property Rights
WHO/WTO – World Health Organization/World Trade Organization

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I. Introduction

Very few industries can claim to be as dynamic, or as important, as the pharmaceutical industry. With the ever-changing scope of infectious and chronic diseases, drug manufacturers have responded aggressively over the years with innovative products designed to combat public health threats. Equally as aggressive has been the response from the governments where medical needs have been the greatest. From changes in patent protections to strong-arm government leveraging, what has become evident over the past thirty years of debate is the presence of an on-going chess match between the affordability of medicine and the accessibility to medicine. More affluent countries are somewhat insulated from some of the issues in this debate because health insurance, public or private, is more widespread and also because, on average, those without health insurance are slightly more capable of shouldering the out-of-pocket expenses associated with healthcare needs. On the other hand, health insurance in less developed countries may not be as widespread or as comprehensive, so economic differences can play a large role in access to healthcare as out-of-pocket expenses for medicine tend to be much more exorbitant.

Latin America, as a whole, is no exception to the less developed country scenario, and much has been written about the pharmaceutical industry's involvement in the region. The literature discussing the last thirty years, in particular, has detailed several changes to international trade agreements, domestic regulatory structures, and strategies surrounding growth in developing Latin American nations. Interestingly enough, several of the articles have overlapping features that help to identify the issues complicating the balance between accessibility and affordability. In reviewing the material, what has become apparent is that the complexity of the industry, the impact that the industry has on the population, and the size of the industry's footprint have all created a series of challenges unlike those of other industries. Addressing every challenge is a daunting task and far beyond the scope of this research.

Due to the depth of the pharmaceutical industry, this paper limits its scope to the current security-related challenges affecting the pharmaceuticals sector in Latin America. In

addition, this project also posits that current challenges to the industry are the result of two things—need and opportunity. To be more specific, the need in question is one of expanding access to essential medicines while the opportunity is in one in which criminal organizations are able to capitalize on financial incentives resulting from this need. Using multiple approaches of analysis to investigate the idea of *need* and *opportunity*, this project attempts to answer the following question:

What are the main security threats to the pharmaceutical industry in Latin America?

Justification for this research is two-fold. One part stems from the rise in various types of crime associated with pharmaceutical products over the past thirty years. In addition, because products are ingested into the bodies of patients who consume them, an increase in criminal activity poses a serious public health issue since unwitting patients are now being exposed to a greater number of risks that may lead to undue injury or death. As such, it is to identify relevant security threats in order to best mitigate the risks associated with them. The second part stems from professional necessity. As a security professional in a rapidly changing organization, a primary objective was to train and develop a team charged with monitoring and analyzing Latin American events in order to gauge impact on operations and to craft predictive intelligence products that enable key company stakeholders to make decisions to mitigate threats before incidents occur. Although this objective sounds easily achievable, several challenges needed to be addressed.

First, contractual issues left no room to provide input in the recruitment process for prospective analysts. Second, the analysts assigned to the team live in remote portions of the country away from major cultural hubs; knowledge of international affairs or Latin American history is lacking. Third, education levels within the team vary with only a few having any sort of advanced education. In addition, none have ever had experience with studies in human behavior or with risk management. Fourth, none of the analysts have ever worked in an intelligence-driven function; the concepts of rapid decision-making and the 'speed of execution' are completely foreign. Fifth, none of the analysts have prior experience with the pharmaceutical industry. This project reflects the efforts employed to close the greatest gaps of knowledge within the analyst team – an understanding of bias,

risk and threat; historical knowledge of the pharmaceutical industry in Latin America in addition to socio-economic knowledge of the people; an understanding of modern risks over the past decade.

First, three separate management tools are used to analyze vulnerable elements within the pharmaceutical industry's operating environment in Latin America. Elements are then analyzed through a proposed model to determine whether there is credible threat. Second, a series of interviews with security professionals in the pharmaceutical industry provides first-hand perspective of ongoing and emerging threats. Third, the theoretical concepts are used to demonstrate how perception of risk may vary among the interviewees. Fourth, a collection of articles is used to conduct a historical analysis of the pharmaceutical industry in Latin America to establish the legitimacy of need and opportunity as underlying factors. Fifth, publicly available data from the Pharmaceutical Security Institute (PSI) is used to help validate some of the conclusions made in the historical analysis prior to moving into a section on modern threats—also supported with articles.[†] Sixth, a conclusion summarizes the findings of this research. Limitations of this research are also discussed. Lastly, recommendations for future research topics are provided.

II. Methodology

Part 1

A PESTEL analysis, Porter's 5 Forces analysis and SWOT analysis are used to identify trends or characteristics within the pharmaceutical industry's operating environment in Latin America. While the traditional objective of these tools is to identify strategic business opportunities, their design makes them easily transferable to security-focused analyses that aid in isolating key areas where risk may be present at all levels of the industry.

[†] Due to the sensitivity of information contained in the annual PSI Situation Reports, PSI does not authorize the disclosure of any material that is not already disseminated for public use through the PSI website. Because PSI member organizations willingly self-report information concerning security-related matters as a means to develop best practices for the industry, the precept of confidentiality must be strictly enforced.

Once possible vulnerabilities are identified through the traditional analysis tools, they are analyzed through the proposed model below. There are several ISO accepted models available for risk management, but many of them are overly academic and do not adequately support the secondary justification for this research – to train and develop a team of analysts with little or no background in analysis in order to help them understand critical thinking and risk. For full disclosure, the model below is not an ISO accepted model. However, it does incorporate and reflect aspects of ISO accepted models in a simplified format that is easy for team members to follow.

Figure 1: Threat Assessment Model

The following definitions add clarity to the structure of this model and answer any questions that a team member may possibly ask.

- Vulnerabilities are internal or external weaknesses within a system or organization that may expose the country to risk. For example, an internal vulnerability can be a flawed hiring process for personnel.
- A security risk is any event that could result in the compromise of organizational assets (Talbot & Jakeman, 2008).
- Actors are anyone or anything capable of exploiting vulnerabilities. Actors can be natural or manmade events, such as earthquakes or explosions at facilities.
- Intent represents the intrinsic motivations compelling an actor take action on a risk. For example, is the actor's intent to harm personnel or to disrupt business operations?
- Capability represents the actual ability to carry out a desired action. In addition to intent, capability is quite possibly the most important piece in this model because it determines whether a risk can become a threat. For example, an actor with low intent and high capability is not a credible threat, and neither is an actor with high intent and low capability.

- A risk does not become a credible threat until it is shown that an actor has high intent and high capability to exploit vulnerability.

Part 2

Interviews with six security professionals in the pharmaceutical industry provide real-time knowledge of ongoing and emerging security threats. All names and professional titles of interviewees are removed to maintain operational security and to preserve personal safety and security of contributing interviewees and respective family members. All interviews are approximately 30 minutes in duration and telephone is the only interview medium employed. The following questions serve as guiding prompts for discussion.

Thank you for your participation in this interview. Please consider the following questions and formulate responses that will not compromise the safety of any individual or the integrity of any enforcement measures.

- *Question 1: In your opinion, what are the main security threats to the pharmaceutical industry in Latin America?*
- *Question 2: Of these, which threat(s) do you consider more important than others? Please explain.*
- *Question 3: In your opinion, what are the underlying causes attributable to the threat(s) mentioned?*
- *Question 4: In your opinion, are there any transnational components to the threat(s) you identified, or do they only possess regional characteristics? Please explain.*

****Note: For this research, Mexico is considered a part of Latin America where often it is categorized as North America.*

Questions 1 and 2 are designed to generate subjective responses that can then be prepared for comparison. These questions are also designed to test for bias in perception of risk and threat by demonstrating that what may be identified initially may not be that serious of a threat after all. Question 3 is designed to test the hypothesis that *need* and *opportunity* are the underlying causes for threats identified through analyses in Parts 1

and 2. Question 4 is designed to test for bias attributable to geographic location in the region and proximity to the threat identified.

All questions are designed to elicit responses specific to the risk perception and threat assessment as opposed to responses focused on closed, active or upcoming enforcement operations. As a fail-safe measure, interviewees received questions ahead of time to ensure adequate preparation and the prevention of any possible leaks of government or corporate classified information. Qualitative analysis of interview content is used to extract the main theme of each threat identified during the course of the interview to determine what the true threats are to the pharmaceutical industry in the region.

Part 3

A review of literature discussing affect and bias is reviewed. The concepts identified in the literature review are then applied to the interview results to help explain why some of the interviewees may have responded with the answers they provided.

Part 4

A historical analysis of the past three decades helps to identify the major shift in trends in the pharmaceutical industry. The purpose of this analysis is to determine whether these trends have ultimately led to the underlying causes for some the threats identified in Part 1 by creating both need and opportunity. A portion of this historical analysis examines the case of Brazil and its management of the HIV/AIDS public health crisis it endured. Selection of Brazil as a specific example is attributed to the case's impact on the pharmaceutical industry and the international community.

Part 5

Statistics from the PSI, a non-profit, membership organization dedicated to protecting the public health, sharing information on the counterfeiting of pharmaceuticals and initiating enforcement actions through the appropriate authorities (Pharmaceutical Security Institute, 2013) are presented to confirm the findings of the historical analysis in order to determine whether there has been an increase in criminal activity resulting from the

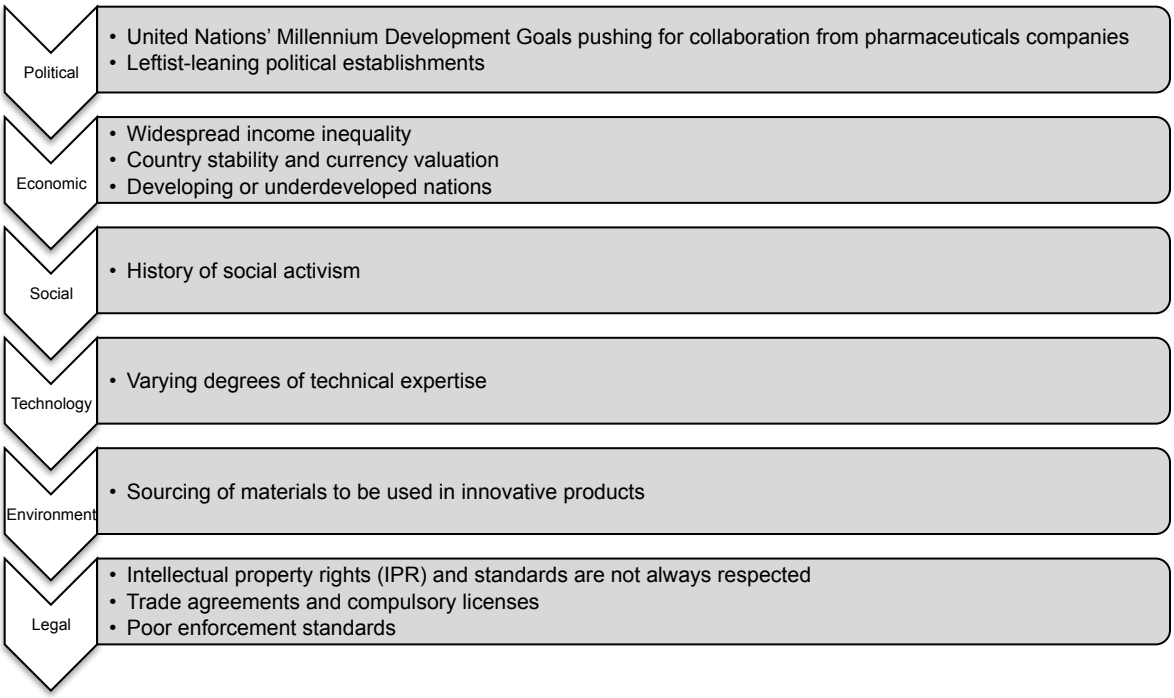
presence of underlying causes. Next, the discussion transitions into an in-depth review of the security threats in order to validate the underlying causes of criminality.

III. Analysis

Before moving forward with this section, it is important to remind the reader that the secondary objective of this project is to develop a practical tool that can be implemented into an existing operation as a means to train analysts. The points identified below are the result of the team's personal experience since creation or the experience of companies who previously reported statistics to the PSI for industry analysis. Upon completion of all three analyses, the vulnerabilities are pushed through a model representing a series of questions to determine whether a vulnerability poses enough risk to become a credible threat. The reason for this model is to teach analysts who are not trained to think critically to analyze a problem in a structured fashion. The goal is for each analyst to eventually internalize this step-by-step procedure.

The PESTEL analysis identifies regional, macro-level issues that may serve as underlying contributors to some of the risks identified. Although there are other noteworthy items for strategy and business development that can be identified through a PESTEL analysis, applicability to this project is limited to items that can impact the security environment.

Figure 2: PESTEL Analysis of Latin America



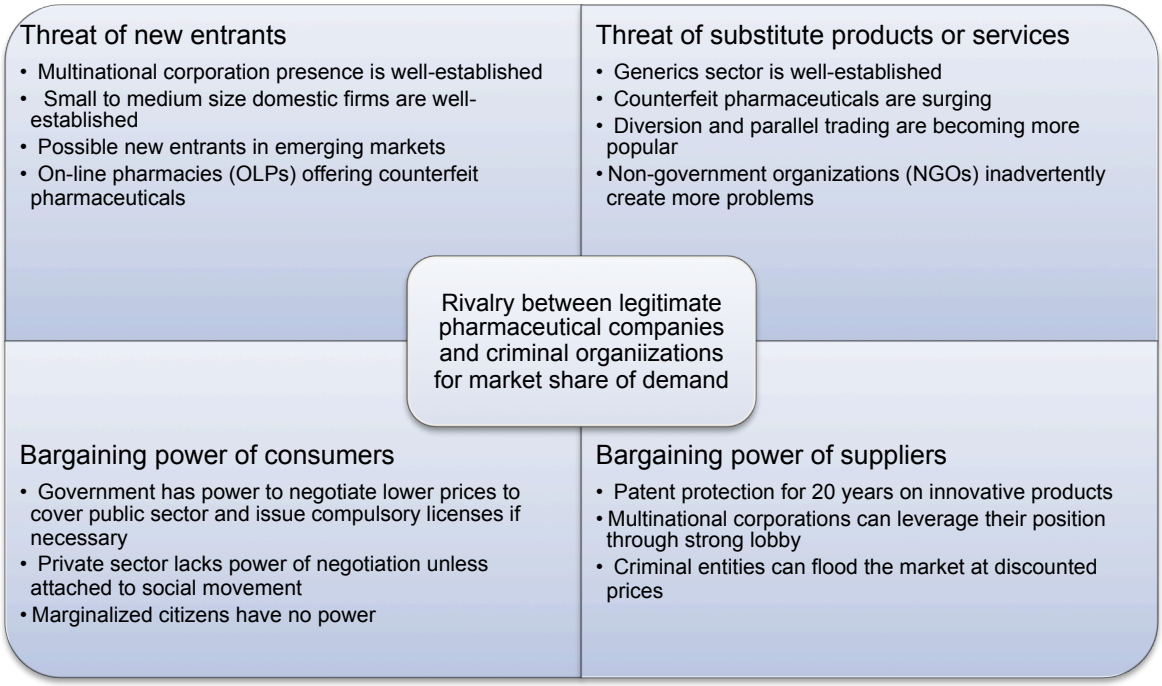
The following items are likely to expose the industry to risk for the following reasons. Items are briefly described her and detailed in subsequent sections of this project.

- United Nations' Millennium Development Goals call on the major pharmaceutical companies to push for wider access to medicine, suggesting the existence of a coverage gap that may breed criminal activity.
- Leftist governments are likely to promote public health programs, thus creating a demand for cheaper medicines. Criminals can capitalize on this situation because governments will often look for the lowest-priced option, and legitimate products are often too expensive to sustain.
- Income inequality is likely to result in a shortage of medicines for marginalized persons, meaning there will always be a constant demand for lower-priced products.
- Country stability and currency valuation are often the main focus for government entities. While governments focus on stabilizing the economy, criminal organizations will likely manage to evade detection.

- Increases in social activism will draw wider scrutiny over the high price of some medicines. Increased awareness may emphasize the need for lower priced medicines.
- Varying degrees of technical expertise are important because countries without a pharmaceutical manufacturing sector are likely to rely on imports to meet demand. Without the proper knowledge base, detection of counterfeit products may be le lacking.
- Violation of intellectual property rights (IPR) are a growing concern in that products produced in violation of IPR may not be required to meet testing standards. This creates a public health problem.
- Trade agreements and compulsory licenses will affect IPR.
- Poor enforcement standards for IPR violations are a constant problem in the region.

Porter's 5 Forces analysis presents greater insight into the Latin American market for pharmaceuticals. Although this type of analysis is normally reserved for new market entry analysis, the Porter's model enables one to see the pharmaceuticals market from a risk perspective by focusing primarily on the sections covering threat.

Figure 3: Porter's 5 Forces Analysis of the Pharmaceutical Market in Latin America



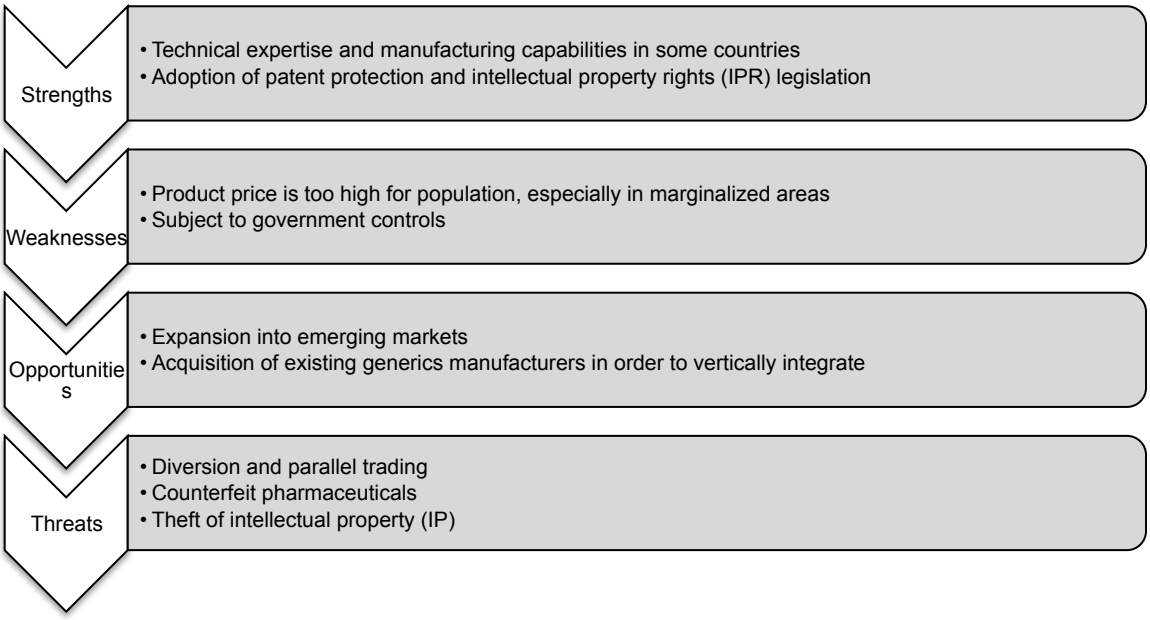
Based on the analysis, the following items pose the greatest risk at the market level. Items are briefly described her and detailed in subsequent sections of this project.

- Emerging markets in Latin America are risky because of the potential for lack of oversight. The industry itself may have a lengthy history in the region, but each country possesses different characteristics at the individual market level. Items such as the regulatory environment and criminal enforcement standards vary greatly.
- On-line pharmacies (OLPs) are a newer phenomenon and have created a parallel market for pharmaceutical products. Legitimate and counterfeit products are sold through OLPs and pose a significant public health risk for several reasons.
- Government power to negotiate and to issue compulsory licenses is a problem because governments can grant manufacturers the authorization to violate patent protection or can threaten companies in the market with licenses as a means to lower prices.
- A large presence of marginalized citizens throughout the region poses a risk because of an increase demand for product. The shortage in medicine ultimately creates an opportunity for criminal activity flourish.

- Patent protection on innovative drugs at times are viewed as being too stringent in that they do not allow for the development of a product. As such, criminal organizations are in a favorable position to produce counterfeits or to divert legitimate products in order to sell them at prices significantly lower than branded pharmaceutical.
- Reduced prices pose a threat by undercutting sales and by forcing manufacturers in the industry to lower prices on existing products.
- Counterfeits pose risks because they are likely to worsen actual patient ailments, and in some cases even lead to death.
- Diversion pose public health risks because products do not follow proper chain of custody procedures and are subject to product tampering or damage in the diversion process.
- Non-government organizations (NGOs) are well intentioned, but in their push to provide access to healthcare to marginalized citizens often times inadvertently distribute counterfeit or diverted products. Funding issues for NGOs are often to blame.

The SWOT analysis enables one to look at internal and external items that may affect operations. However, in order to complete a proper SWOT analysis for this research question, one must make the assumption that the industry is a conglomerate of individual actors operating in unison. Otherwise, a separate SWOT analysis is required for each individual company in the industry. Only the most pertinent vulnerabilities and risks are identified.

Figure 4: SWOT Analysis of the Pharmaceutical Industry in Latin America



Based on SWOT analysis, the following items pose the greatest risk at the industry level. Items are briefly described her and detailed in subsequent sections of this project.

- Violations of intellectual property rights (IPR) and the theft of intellectual property (IP) are becoming more prominent with advances in counterfeiting measures.
- Prices for branded, and in some cases generic, pharmaceutical products remain high. This has drawn the attention of activist groups and both criminal organizations alike in that both view a shortage among marginalized citizens that needs to be addressed either legally or illegally.
- Emerging markets have already been addressed in a previous section.
- Diversion and parallel trading were only partially addressed. While diversion is one half of the risk, parallel trading poses another because some governments promote parallel trading of products. Usually this occurs in locations where the government is responsible for socialized medicine.

The following section compiles all these vulnerabilities and risks to determine whether any of them merit additional scrutiny.

Figure 5: Threat Assessment Model Analysis

Theoretical Analysis Using the Threat Assessment Model

Vulnerability	Risk	Actors	Intent	Capabilities	Credible Threat
UN Goals	Maybe	International community	Wider access to medicines	No	No
Leftist governments	Maybe	Political leaders	Wider access to medicines	Yes	No
Income inequality	Yes	Criminal organizations	Fill a need/profit	Yes	**Yes – counterfeits and diversion**
Country instability	Maybe	Criminal organizations	Avoid detection	Yes	**Yes – criminals continue to operate**
Currency valuation	Maybe	Criminal organizations	Fill a need/profit	Yes	**Yes – counterfeits and diversion**
Social activism	Maybe	Activists	Wider access to medicines	No	No
Varying technical expertise	Maybe	Manufacturers	Profit	Yes	No
IPR violations and IP theft	Yes	Counterfeiters	Fill a need/profit	Yes	**Yes – IP violations**
Trade agreements/patents	Maybe	Government/manufacturers	Stringent IPR/innovate	Yes	**Yes – counterfeits and diversion**
Compulsory licenses	Yes	Government	Wider access to medicines	Yes	**Yes – IP violations**
Poor enforcement	Yes	Criminal organizations	Act with impunity	Yes	**Yes – criminals continue to operate**
Emerging markets	Yes	Criminal organizations	Wider access to medicines	Yes	**Yes – counterfeits and diversion**
OLPs	Yes	Counterfeiters	Fill a need/profit	Yes	**Yes – counterfeits and diversion**
Government power	Maybe	Government	Wider access to medicines	Yes	No
Marginalized citizens	Yes	Criminal organizations	Fill a need/profit	Yes	**Yes – countereits and diversion**
Counterfeits	Yes	Counterfeiters	Fill a need/profit	Yes	**Yes – counterfeits and diversion**
Diversion & Parallel	Yes	Criminal organizations	Fill a need/profit	Yes	**Yes – counterfeits and diversion**
NGOs	Maybe	Criminal organizations	Wider access to medicines	Yes	No

Vulnerabilities that have earned the designator of credible threat are are identified in bold. Justification for each threat determination is presented through discussion and the use of additional literature for support prior to moving forward with comparisons to material gathered over the course of interviews.

IV. Results

To understand the outcome of the training model analysis one must first define threa
'Threat' refers to any actor with the capability and intent to exploit vulnerabilities. Usir
an example from another industry, guerrilla groups in Latin America are considere
threats to the oil industry because they intend to disrupt operations along pipelines
rural areas and maintain the capability to do with explosive devices and attacks c
infrastructure. With that definition clarified, one can return to answering the researc
question below.

What are the main threats to the pharmaceutical industry in Latin America?

Although several vulnerabilities and risks are identified through analysis tools, only
handful of actual threats become evident when asking sequential questions at each step
the process. Moreover, in each step of the process one begins to see that with structure
thinking a pattern of trends emerges, and that the assortment of vulnerabilities ca
ultimately be classified under three main security threats listed below.

- *Threat #1: the increase of counterfeit and diverted pharmaceutical products*
- *Threat #2: the ability of criminals to operate in the region*
- *Threat #3: violations of intellectual property rights and intellectual property thej*

For further clarification, the following definitions are applicable to Threat #1 and to the
terms 'counterfeits' and 'diversion' (or any derivative thereof, including 'parallel trade')
used throughout the remainder of this research project:

- "Counterfeit medicines are products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. This definition applies to both branded and generic products (Pharmaceutical Security Institute, 2013)."

- "Illegal diversion occurs when a genuine pharmaceutical product is approved anc intended for sale in one country, but is then illegally intercepted and sold in another country (Pharmaceutical Security Institute, 2013)."

Review of the threats above leads to the following questions: Are there any underlying factors that may be responsible for the existence of these threats? Through a series of additional questions one can develop succinct assumptions regarding underlying factors, actors, and threats. In the following section, a question is posed for each threat. Immediately following is the assumption one can make pertaining to the threat.

- *Threat #1: Who benefits from counterfeit and diverted pharmaceutical products?*

Assumption: Criminal organizations benefit directly because they are generating a sizeable profit by selling phony or stolen medicines.

- *Threat #2: Why are criminals able to operate in the region?*

Assumption: Criminals are able to operate with relative ease because there is nothing to influence a change in behavior.

- *Threat #3: What is the impact of IPR violation or IP theft?*

Assumption: IPR violation or IP theft result in heavy financial loss for pharmaceutical companies.

All assumptions allude to an element of criminality, and in pursuing this line of thinking, the issue then becomes a question of what criminality entails. Simply stated, crime is driven by two existing conditions – need and opportunity. Need implies a weakness or vulnerability in a system, while opportunity implies the possibility of exploiting that weakness or vulnerability. However, exploitation does not always occur because the incentive to act may not always be present or sufficient. Though, in instances where criminal exploitation is present, the opportunity for financial gain is also present. If this correlation holds true, then one can conclude the following: Need and opportunity are the underlying causes for the presence of the security threats to the pharmaceutical industry in Latin America.

Interview results

To test the idea that need and opportunity are underlying causes, six security professionals in the pharmaceutical in were interviewed to gain real-time insight on ongoing and emerging threats to the region.
As a reminder, interview prompts are provided below.

- *Question 1: In your opinion, what are the main threats to the pharmaceutical industry in Latin America?*
- *Question 2: Of these, which threat(s) do you consider more important than others? Please explain.*
- *Question 3: In your opinion, what are the underlying causes attributable to the threat(s) mentioned?*
- *Question 4: In your opinion, are there any transnational components to the threat(s) you identified, or do they only possess regional characteristics? Please explain.*

Identity for all interviewees remains anonymous throughout the discussion. All interviews were conducted via telephone and averaged approximately 30 minutes in duration. Some deviation from the prompts did occur as the conversation progressed into different areas of pharmaceutical security, but overall, discussions were very focused. Due to the lengthy conversations and the fact that interviews were conducted in either Spanish or Portuguese, only translated synopses of the full transcripts are presented in Appendix A.

Questions 1 and 2

A large number of threats are identified as having a significant impact on the pharmaceuticals industry in Latin America. As suspected, counterfeit pharmaceuticals are among the threats most mentioned during interviews. Cargo theft also ranks equally as high. However, in looking at the other threats mentioned, piracy, product theft and parallel trade are also mentioned at least once. When considering each of these threats in addition to cargo theft, all four individual threats actually represent various components of diversion. With that said, one can conclude that diversion is mentioned twice as much

as counterfeits. What is surprising is that IPR violations and IP theft do not appear in any of the interviews. One explanation is that perhaps industry professionals consider these to be sub-threats of counterfeiting and not a stand-alone category since, as mentioned in the discussion of modern trends and threats, increased sophistication of counterfeit products is now being seen across the region. A secondary explanation is that IPR violations and IP theft may actually be much more prevalent in other parts of the world as opposed to Latin America. A third explanation may be that detection and enforcement of standards on these threats may be much stronger in other parts of the world as well.

Another surprising result is that the threat to personnel ranks highly among interviewees. The presence of this threat among interviewees makes sense given the region's ongoing income inequalities, underdevelopment and easy access to weapons; crimes associated with this particular threat are often economically driven. Moreover, due to the proliferation of criminal organizations in Latin America, infiltration of criminals into security forces is highly likely and may contribute to underreporting and an overall deterioration of the security environment.

Once again, lumping parallel trade with cargo theft into the category of diversion, interviewees mentioned diversion equally as much as counterfeit pharmaceuticals. On the other hand, despite the heavy mention of threat to personnel security, interviewees do not deem this threat as important as cargo theft or counterfeit pharmaceuticals.

Question 3

In response to the hypothesis that need and opportunity are underlying factors for the identified threats, one can argue that the hypothesis is confirmed because lack of access to essential medicines and profit motivation are the most common responses. Lack of access is indicative of a need while potential profits are indicative of an opportunity. Counterfeits can be attributed to both need and opportunity in this case being that they exist as a result of an unmet need and continue to exist as a result of the opportunity for financial gain. However, alternate explanations should also be considered.

One can argue that in interview results, the mention of border control issues, enforcement issues failed intervention policies and lack of education directly contribute to exploitation of opportunity and can be lumped under the banner of detection and enforcement. Poor enforcement facilitates the commission of crime and propagates the problems of counterfeit or diverted products either by overlooking offenses or by establishing punishment standards that are too week to serve as deterrents to crime. Poor education, as indicated earlier, creates an overreliance on supposed authority figures, and impacted citizens often purchase phony products as a result.

An alternate, fascinating underlying reason that was mentioned is the problem with ego and vanity. Although not the exact type of need this research attempts to explore, this reasoning does strongly suggest the existence of a legitimate need for people to have prescribed positive self-image. One supporting argument is the notion that men are ashamed of losing virility and strength as they age due to a natural loss of testosterone. Criminal organizations certainly see the opportunity for exploitation and profit, which ultimately explains why erectile dysfunction medicines and anabolic steroids are two of the most heavily counterfeited products, not only in Latin America, but worldwide.

Question 4

In response to whether any of the threats carry transnational components, the overwhelming answer is yes; however, one interviewee does mention that some threats are more region-specific. Regardless, if one once again lumps parallel trading into the category of diversion, the combined ranking places diversion above all others except for counterfeits. However, criminal impunity, enforcement issues and weapons smuggling can all be lumped under enforcement with a combined ranking equal to that of diversion. Moreover, both diversion and enforcement issues often entail the presence of product that is intended for one country being sold in another country, thus implying the presence of transnational characteristics for these particular issues. This is important because without disclosing each interviewee's geographic location or any identifiable information from the transcripts, one can mention that four of the six interviewees identified the same source for a particular type of threat. Relative distances from the source to the

interviewees account for why a particular threat is not considered a threat by all sources; a lack of exposure is to blame.

A focus on smuggled weapons creates a lack of attention to the problem from authorities. In addition, as hinted at in some of the interviews, governments in some cases overlook the counterfeit and diversion problem because they are primarily concerned with acquiring low-priced medicines regardless of public health risks or because the domestic economy needs the supplementary revenue generated from the trafficking of counterfeit or diverted pharmaceutical products.

Impact of affect and bias on interviewee perceptions

To understand how affect and bias impact perception of risk, one must first understand exactly what they are. The affect heuristic (affect) is an intuitive hunch that one associates to a particular stimulus, thus heavily influencing decisions in addition to the perceived benefit resulting from those decisions (Slovic & Vastfjall, 2010). Affect contains an emotional component that focuses on the amount control that an individual has in a given situation (Slovic & Vastfjall, 2010). Thus, when people feel emotions that are accompanied by certainty appraisals (positive affect), they are more likely to feel certain in subsequent situations than when they feel emotions accompanied by uncertainty appraisals (negative affect), which produce more uncertainty in subsequent situations (Tiedens & Linton, 2001). Thus, emotion-driven affect can weigh on perception and behavior, but it remains difficult to understand exactly how emotions can produce profound changes in perceptions and behaviors (Lowenstein, 2007).

To clarify, perception of risk in humans is strongly influenced by cognitive processes (Shuhama, Del-Ben, Loureiro, & Graiff, 2008). Although true, influence may also be the result of existing mental constructs. Biases, as they are more commonly known, often lead to misinterpretations of warnings and indicators (Heurer, 1999) because they are often heavily ingrained in the human psyche. Unless individuals can deconstruct these mindsets, underlying desires to make data fit accordingly into comfortable frameworks will ultimately result in flawed interpretations and perceptions of risk (Heurer, 1999). Bias is also individualistic in nature, so comparison among individuals is important in

order to gauge whether information related to disparate threats is processed in similar fashion (Heilbrun, Wolbransky, Shaw, & Kelly, 2010). Comparison among individuals enables determination of whether the distinct features of one risk are perceived differently from the distinct features of another risk (Heilbrun, Wolbransky, Shaw, & Kelly, 2010). Moon and Conlon support claim that the same particular status, which benefits people in positive situations, might actually harm people in negative performing situations (Moon & Conlon, 2002).

The difference in responses between Questions 1 and 2 is therefore attributable to affect and bias. While interviewees identified the threat to personnel security as one of the main security threats to the industry, none of the interviewees deemed the threat serious enough to classify it as more important than other threats. This alludes to a possible emotional attachment driven by negative affect that led to an initial designation of security threat. It also remains possible that interviewees may have reduced the level of perceived threat after considering wider industry impact.

Moving forward, bias is not the same as affect. While affect leads one to prescribe a degree of risk to a situation based on emotion or intuition, bias leads one to dismiss (or accept) a degree of risk based on experience and emotional recall in similar situations. The problem with this is that, due to affect and bias, individuals differ in risk identification capabilities. Thus, whereas most individuals may seek to avoid the consequences of risk, only some individuals are truly capable enough to recognize the threats associated with risk when they occur (Robinson, Meier, & Vargas, 2005).

As such, one can argue that affect and bias are also attributable to the non-reporting of IPR violations or IP theft. Considering some of the possibilities previously addressed in the results section, biases resulting from things such as weak enforcement standards may have created a sense of apathy that enables interviewees to dismiss the nature of the threat. A lack of exposure to IP issues may also explain why interviewees may not have perceived true risk earlier. In addition, risk factors vary greatly and tend to fluctuate, and the types of risk factors deemed important depend on the types of decisions that need to

be made (Tolman & Rotzien, 2007). If interviewees are not making decisions on IP issues, then it is unlikely they will ever be considered threats.

Interpretation of results

One can say that only the first two threats have been confirmed as credible. Meanwhile, the threat to IP remains hidden to, or unidentified by, industry professionals operating in Latin America. Although the existence of IP threats is seen in the industry, interviewees failed to confirm the credibility of this any IP issues.

The research and development process for innovative products may be to blame. Given the time and money required to develop an innovative product, in addition to the competitiveness existing in the industry, it is highly unlikely that any information regarding such projects is communicated broadly. Only key stakeholders have intimate knowledge of project details, and there is a strong possibility that the industry professionals interviewed are not members of the key stakeholder group. Thus, interviewees may legitimately interpret a large seizure of counterfeits or the disruption of an advanced counterfeiting facility at face value, never considering the possibility that either may represent criminal technological advancements achievable only through stolen or violated IP.

A secondary explanation is the possibility that the industry professionals interviewed are simply not aware of any recent or current trends indicating the presence of threats to pharmaceutical-related IP. A lack of information sharing may be to blame. To qualify this statement, the expression pharmaceutical-related IP pertains to trade secrets or patented information, such as manufacturing processes or research-related data, used in the development of innovative products. Protection of IP is the responsibility of the companies in the industry and not of enforcement officials in the region. Given the sensitivity of the information, IP protection entails the non-disclosure of information to anyone other than stakeholders with a critical need to know; this group of stakeholders often does not include enforcement authorities.

In light of this, one can say the role of enforcement authorities is to focus on preventing already manufactured counterfeits from entering and propagating in the region rather than preventing the loss of IP. Unless enforcement officials are made privy to sensitive information, seizures and closures indicative of sophistication may go unnoticed and subsequently unreported to pharmaceutical companies. On the other hand, the argument against sharing information is that in Latin America, the security forces in certain parts of the region are often unreliable and unworthy of trust. As long as this situation remains, it is possible that IP threats will not be managed accordingly due to late, or no, recognition by industry professionals.

As stated earlier, the threat to personnel security is a surprising discovery in the course of this research. Consider the following explanation. The presence of counterfeit and diverted products is easily quantifiable because there are recorded metrics, such as the number of arrests or seizures and year-over-year trends that can be established. The true size and detection rates of the problem are irrelevant because arrests and seizures are tangible metrics nonetheless. With personnel security, metrics are also available as are year-over-year trends, but these are often the result of after-the-fact reporting. In addition to this objective component, personnel security is somewhat nuanced and also carries a subjective component. Thus, affect and bias may cloud judgment of risk and determination of threat before the fact.

Although counterfeit and diverted products have a significant, measureable impact on the pharmaceutical industry, the threat to personnel security does not. One can measure profit loss, adverse reactions to phony medicines and theft of product. One can even measure the number of kidnapped sales representatives or the number of assaults mid-level executive experience in a given month. What is immeasurable is the degree of fear and emotional impact stemming from such incidents. For personnel in areas of Latin America with higher frequencies of occurrence, these types of threats resonate more in the mind, especially if one has previously been the victim of a similar crime or personally knows someone who has. Any previous experience, either personal or relative, is likely to skew results. Moreover, media influence in Latin America is noteworthy. An interviewee

subjected only to negative news about the security environment will probably perceive personnel security risks to be greater than they may actually be.

For example, the loss of a sales representative due to kidnapping or homicide is tragic and may be reported in the local news over a 24-48 hour cycle. The incident is likely to stay in the minds of other representatives in the sales force and other members of the organization. For this group of individuals, the threat to personnel security is high. However, from a wider viewpoint, the threat is relatively minor because other sales representatives can fill the remaining gap to ensure business continuity. Counterfeit and diverted pharmaceuticals, on the other hand, carry greater implications implications, such as widespread injury or death resulting from adverse reactions to counterfeit products. From a public health perspective, this is a tragedy. From a pharmaceutical industry perspective, this is a nightmare for liability and reputation, and significant media coverage on the issue could last for prolonged periods of time, especially in the event of litigation.

V. Discussion

Knowing the security threats are present is one thing. Understanding why they are present is another. The history of the Latin American pharmaceutical industry provides insight into the underlying reasons of need and opportunity. A portion of the following material focuses on the Brazilian government's response to the HIV/AIDS epidemic because of the implications of the case; the pharmaceutical industry's counter-response is also presented. The remainder of this section focuses on the most recent history, where the consequences of need and opportunity have become most visible.

History

"Pharmaceuticals are the most important health-related products that are traded, accounting for 55% of all health related trade (Smith, Correa, & Oh, 2009)." Although true, a key observation is that the price of branded pharmaceutical products has consistently remained high even by developed-world standards. Regardless, the demand for pharmaceutical products never waned, especially in developing countries where

access to effective and affordable medicines was necessary to reverse the rising trend of high mortality and morbidity from infectious and non-communicable diseases (Kamal & Bailey, 2003). The traditional problem, however, has been that "in these countries access to essential medicines is often limited because of widespread poverty, dependence on assistance from the global community, and imperfect governance (Van Puymbroeck, 2010).

Historically, dependency and imperfect governance contributed to creating barriers to access, but price was the biggest concern because it compounded on the problem of poverty. Moreover, a shortage of health insurance in impoverished areas of Latin America meant up to 90 percent of people in low-and middle-income countries paid out-of-pocket for medicines (Van Puymbroeck, 2010). Providing medicinal products at prices that patients can afford became a challenge (Martin, 2010).

The need grew so high that the international community declared the expansion of access to essential medicines one of the United Nations' Millennium Development Goals (United Nations). Implementation has been challenging given issues such as income inequality; the lesson learned is that without appropriate safety nets for the poorest and most marginalized sectors of society, reform will remain counter-productive (Khan, 2009). Latin American governments have taken steps to address inequality by offering public health insurance. However, sustainability of such programs has always been a concern because governments often operate with limited tax revenues. Moreover, in some Latin American countries "weak infrastructure and enforcement systems mean that payment of taxes and other contributions are essentially optional (Balabanova, McKee, Mills, Walt, & Haines, 2010)." Thus, funding ambitious healthcare programs has always represented a major obstacle given the demands of large populations and ongoing economic uncertainties that tend to dictate the budgetary allocation for public services (Kermani, 2006).

This means that where the government has provided healthcare, recipients were often unable to judge the quality and type of care due to the lack of alternatives resulting from the government's inability to pay for costly treatments. Thus, price to a degree has

determined healthcare policy. Activists view this as unacceptable because truly functional health systems should ensure access to medically necessary and medically appropriate care (Esteves, 2012). Several activists continue to argue that price reductions are necessary because affordable, accessible pharmaceuticals provide a cost-effective solution for the poor throughout Latin America (Cohen, 2006).

Reforming policy has been a constant debate, particularly the issue of generic pharmaceutical products. Stakeholder rights are partly to blame because a viable generics sector affects a broad range of actors. Lower-income patients receive the best therapeutic options at the lowest possible cost, and physicians provide service for all patients in a way that meets their treatment needs (Araujo, Caporale, Stefani, Pinto, & Caso, 2011). Governments have used generics as a solution to the problem of expanding care during public health crises (Homedes & Ugalde, 2005). Perhaps the most noteworthy example in terms of impact is Brazil during its fight against the HIV/AIDS epidemic.

In the 1980s, branded anti-retroviral (ARV) treatment options for HIV/AIDS were available through some of the major pharmaceutical companies at a high price. This posed two significant problems for the Brazilian government—first, an unmet need for treatment existed, particularly in marginalized areas of the country; second, a challenge for containment of a rapidly spreading disease that was not limited to just the marginalized areas of the country. Recognizing both needs, the government adopted a system of universal healthcare designed to provide ARVs to all infected citizens, rich or poor, regardless of cost. Guaranteeing long-term funding for healthcare initiatives was both problematic and overly ambitious because Brazil's size as a country made the provision of ARVs for all citizens a difficult commitment to fulfill (Kermani, 2006). The main concern was that supplying the drugs one year, but not being able to meet patient needs the following year, was the worst scenario imaginable (Jorge, 2011).

Much to the dismay of the major pharmaceutical manufacturers, the Brazilian government's solution to this problem was price stabilization achieved through the development of domestic manufacturing capabilities focused on the production of generic pharmaceutical products. At the time, loopholes in the Brazilian patent laws permitted

reverse engineering of branded products for the production of generics as long as manufacturing processes were not copied. Brazilian generics were considered true generics if they were pharmaceutically equivalent, and if their respective bioavailabilities after administration in the same molar dose had similar effects with respect to efficacy and safety (Barra & Albuquerque, 2011). Despite the outrage, domestic manufacturing presented an excellent opportunity to curtail the HIV/AIDS threat and to widen access in a sustainable fashion.

The pharmaceutical industry responded with concerns that although products were licensed, generics manufacturers did not need to repeat clinical trials and products only needed show therapeutic equivalence by demonstrating pharmaceutical equivalence through in vitro and in vivo testing—demonstrating the same pharmaceutical specifications and/or bioequivalence to prove they have the same absorption and distribution rates in the bloodstream (Barra & Albuquerque, 2011). On the other hand, branded pharmaceutical products were licensed based on safety, quality and efficacy data produced in controlled clinical trials (Barra & Albuquerque, 2011). For the industry, the production of generics was a serious problem because Brazil tended to label these untested copies as true generics (Valente, 2006). Regardless of financial motivations, the ensuing concerns for the major pharmaceutical companies at this point were the health and safety of the patients and the possibility that other countries might study Brazil's strategy in order to develop manufacturing capabilities in order to support their own public health initiatives (Kermani, 2006).

The result was the 1994 Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement that extended patent protection on new products, and on the processes by which drugs are made, for a minimum of 20 years (Kamal & Bailey, 2003). Countries that joined the TRIPS agreement touted new standards because they represented a push for stronger intellectual property protection. However, the agreement was not in the best interest of the international community, and the obligation of a 20-year mandate made it increasingly challenging for governments in Latin America to ensure that their populations had access to medicines while simultaneously meeting international trade obligations (Cohen, 2006).

In theory, TRIPS was supposed to protect the long-term interests of both pharmaceutical companies and the governments of Latin America. Unfortunately, TRIPS made the criteria by which the governments of Latin America could justifiably violate patent protection much more stringent. As a result, governments no longer had the same liberties to determine what constituted a public health emergency, thereby limiting abilities to infringe on patent protections in the interest of public benefit. Prior to TRIPS, violations of IP were justified on the grounds of allowing domestic pharmaceutical industries to develop in order to combat epidemics. Ultimately, the TRIPS agreement forced developing domestic industries to be dismantled under industry fears that the proliferation of small laboratories dedicated to the production of no-patent and post-patent generics (Forero-Pineda, 2006) was inevitable in developing countries throughout the Latin American region.

As a result, TRIPS allowed pharmaceutical companies to set higher prices for their products in developing countries, thus complicating the original problem of expanding access (Bjornberg, 2006). The overall consensus from communities and activists groups was that TRIPS favored the interests of the major pharmaceutical companies over the interests of respective country governments in that prior to the negotiation of TRIPS, many countries had excluded pharmaceuticals from patentability to keep their costs down (Van Puymbroeck, 2010). As such, the governments of developing countries were once again forced to limit treatment options for citizens due to price constraints.

Brazil was one of the developing countries greatly impacted by the 20-year mandate. However, using a loophole in the TRIPS agreement, the Brazilian government threatened the major manufacturers of ARVs with the issuance of compulsory licenses to domestic manufacturers. For clarification, a compulsory license under enables a government to allow "a local entity to produce and distribute a good under patent without the consent of the patentee (Shadlen, 2007)." While previously loopholes allowed for final products to be copied as long as processes differed, this loophole enabled a violation of IP under a public health emergency clause. Brazil did not have its own consolidated pharmaceuticals sector capable of producing generics on a large scale, but it did have a collective of

domestic pharmaceutical companies with manufacturing capabilities and labor to support the manufacturing processes.

The Brazilian government leveraged this structure to threaten the major pharmaceutical manufacturers in an attempt to force price reductions for branded ARVs. Most other Latin American countries lacked the capabilities to produce drugs locally, which, in turn, equated to empty threats (Shadlen, 2007). However, in Brazil the threat of compulsory licenses was certainly credible, and companies in the industry responded by lowering prices; the degree reduction was unacceptable to the Brazilian government, so it acted on its threat and issued compulsory licenses.

Impacted companies sought injunctions and compensation for lost profits in court. In what became known as 'the Merck case,' the courts ruled that the use of compulsory licenses was not theft, but rather a safeguard protected under international law (Van Puymbroeck, 2010). The legal decision enabled the Brazilian government to curtail the HIV/AIDS epidemic in to a very manageable problem. Brazil was fortunate in its experience, but the greater implication of this case is as follows. Other countries in Latin America would have had no option but to purchase branded medicines as a result of underdeveloped or non-existent manufacturing capabilities. Following the legal decision, the members of the World Trade Organization (WTO) realized the potential negative impact of TRIPS on public health in developing countries.

Transitioning to the international community, in 2001 members of the WTO agreed on a modification to TRIPS that became known as the Doha Declaration (Kamal & Bailey, 2003), which ultimately gave primacy to public health over commercial interests. Despite the fact that the 20-year mandate remains in place since its adoption, as part of the Declaration least-developed countries are now exempt from drug patenting rules until 2016 (Kamal & Bailey, 2003). In addition, countries that did not grant patents before 1995 did not have to begin doing so until 2005 (Shadlen, 2007), giving developing countries the opportunity to establish or improve a domestic pharmaceuticals sector. In short, the Doha Declaration allowed least developed countries to continue guaranteeing access at prices that were affordable and sustainable. Unfortunately, the stability created

under the Doha Declaration was not permanent, and this became evident with the introduction of Free Trade Agreements (FTAs), negotiated between developed countries and lesser-developed countries, that were originally meant to improve bilateral relations and promote growth.

FTAs went beyond the TRIPS Agreement into an area known as 'TRIPS-plus', where some trade provisions were once again determined to be unfavorable for developing countries. Critics argued that these provisions were likely to prejudice public health by making access to medicines substantially more difficult due to newly negotiated high prices for medicines (Cartagena & Attaran, 2009). The belief was that in exchange for more favorable terms of trade for other products, developing countries consequently had to pay higher prices for imported medicines in addition to being affected by stronger intellectual-property rights (Smith, Correa, & Oh, 2009). In addition, others argued that TRIPS-plus provisions led to increases in market exclusivity, which, in turn, led to increased health-care expenditures and diminished access to essential medicines (Martin, 2010).

This had an overall negative effect on "domestic pharmaceutical manufacturers who are the main suppliers of the cheaper generic products necessary to combat the treatable diseases devastating the developing world (Martin, 2010)." The end result of all this reciprocal maneuvering was that once again, price-driven market exclusivity restricted access for Latin American citizens resulting in an unmet need. Given the costs associated with branded pharmaceutical products, actors seeking to acquire lower-priced medicines created a market opportunity for criminal organizations to thrive. This phenomena is seen in the most recent industry history.

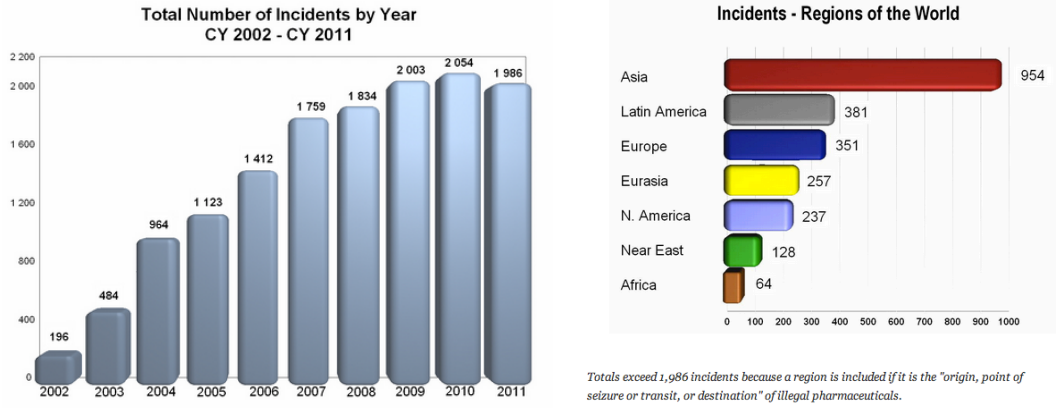
Modern trends

FTAs and TRIPS-plus have had the opposite effect of widening access, and instead have resulted in a widely contested debate over IPR and public health: "innovation and the capacity to obtain new medicines, on the one hand, and access to medicines at affordable prices, on the other (Bernieri, 2006)." Though patent protection for pharmaceuticals was not the only obstacle in access to medicines, it undeniably led to higher prices for

medicines due to perceived 'monopolies', and thus altered the market structure (Cohen, 2006). As a result, concern among non-pharmaceutical actors since the Doha Declaration has been almost universally directed toward making IP regulations more flexible as a means to correct the market in addition to serving as a means to mobilize funding to increase poor countries' abilities to purchase essential drugs (Shadlen, 2007). Moreover, while this debate has unfolded, interested parties have unfortunately become somewhat myopic, and thus have created an oversight in vigilance due to distracted attention. The unintended effect of this oversight is that criminals have been allowed to establish firm operations in Latin America and are now capable of exploiting the opportunity resulting from a coverage gap.

To gain a better appreciation for the size of the problem, the following graphs provided by the PSI show the number of counterfeit and diversion incidents reported through 2011; the second chart reflects only 2011 data.

Figure 6: Total Number of Incidents by Year
Figure 7: Incidents – Regions of the World

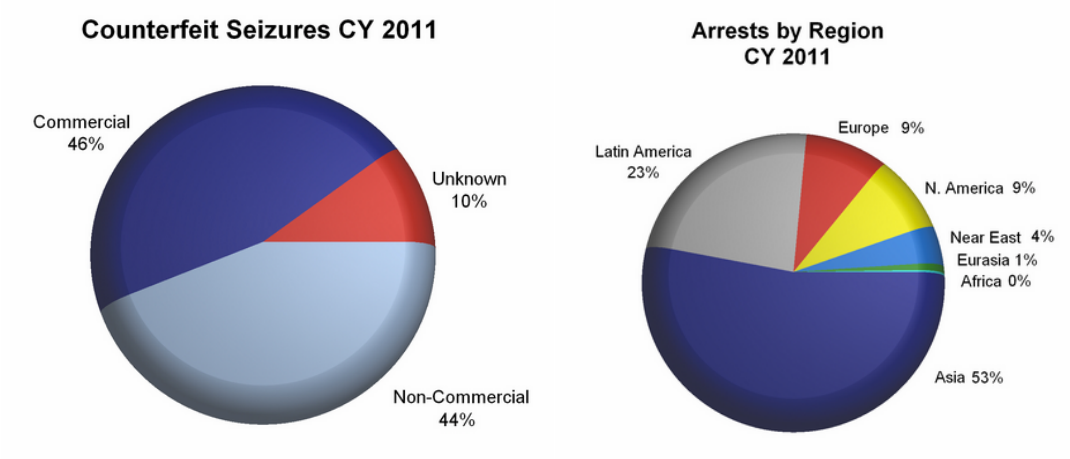


Source: Pharmaceutical Security Institute; Counterfeit Situation: Incident Trends and Geographic Distribution, 2013.

As one can see in the chart on the left, from 2002 through 2011, there was a significant increase in the number of incidents reported with only a small decrease between 2010 and 2011. The chart on the right provides a geographic distribution for 2011 incidents and shows that Latin America ranked second in the total number of incidents detected worldwide. One point to remember is that these figures represent only the number of

incidents detected, so the true size of the problem may be much larger than what is represented in these charts.

Figure 8: Counterfeit Seizures CY 2011
Figure 9: Arrests by Region CY 2011



Source: Pharmaceutical Security Institute; Counterfeit Situation: Incident Trends and Arrest Data, 2013.

The charts above also provide support for the idea that actors seeking lower-priced products are creating a market opportunity for criminal organizations. The chart on the left breaks down the 2011 total of 1986 incidents into commercial seizures (> 1000 doses) and non-commercial seizures (< 1000 doses) (Pharmaceutical Security Institute, 2013). As one can see, the number of commercial seizures is greater, suggesting the possibility of high demand for counterfeit product; at a minimum, the number of commercial seizures represents almost 914,000 doses of counterfeits seized. The chart on the right indicates that of the1311 arrests in 2011, 300 of them occurred in Latin America (Pharmaceutical Security Institute, 2013).

Although stringent patents do play a role in facilitating crime, the reason criminal gangs specializing in pharmaceuticals exist is much more fundamental. In the industry, criminals exist simply because there is a "lack money to buy even cheap medicines, and lack of social and medical infrastructure to deliver them (Van Puymbroeck, 2010)." The problem here is not that a handful of pharmaceutical companies are keeping medicines from people in developing countries through patent protections, but that those governments do not ensure the integrity of pharmaceutical distribution systems (Choate, 2006). Criminals understand this vulnerability extremely well and, as a result, have

created a complex, multi-billion dollar supply chain capable of distributing both counterfeit and diverted pharmaceutical products at prices lower than those of branded products.

In 2010, the global turnover for phony pharmaceuticals was estimated to be $75 billion, a 90 percent increase since 2005 (Bate & Nugent, 2008). Such turnover in counterfeits is high due to the attractive nature of lucrative profits associated with the trade. "Criminal gangs are attracted to pharmaceuticals because of the high value of medicines and the relatively low risk of prosecution (Jessop, 2012)." This is especially the case in the developing nations of Latin America, where a lack of quality oversight and enforcement create the one of the most lucrative potential markets for counterfeiters (Bate & Nugent, 2008). Closer examination helps identify several reasons why this problem persists in Latin America.

First, widespread diseases such as malaria continue to plague the region, and the urgent need for affordable medicines in disease-ravaged developing nations facilitates the continuous expansion of the counterfeit drug trade (Chaves, 2008-2009). For some governments, the "high price of drugs can serve as a disincentive to invest in the development of the healthcare infrastructure that is essential for treatment of these diseases (Shadlen, 2007)." As a result, the "problem of disease remains unbridled in these developing nations because most of the governmental bodies do not have the needed resources to counteract these debilitating issues and implement sufficient sanctions that deter counterfeiters from exploiting the disadvantaged populace (Chaves, 2008-2009)."

Individuals who fall ill are often forced to search for cheaper alternatives in order secure treatment. In some cases, governments that run socialized medical programs also seek cheaper alternatives. Moreover, in some Latin American countries international and domestic non-governmental organizations (NGOs) have intervened to help fill the gap in coverage by purchasing and distributing medicines, primarily in marginalized areas. Despite good intentions, NGOs sometimes compound the problem by buying in bulk to save costs prior to distributing medicines (Bate & Nugent, 2008). Unfortunately, in order to acquire the necessary amounts to provide proper coverage, NGOs often secure medical

supplies through Internet purchases at online pharmacies (OLPs) where the prices are heavily discounted; sadly, most OLPs are managed by criminal entities that care about nothing other than profit. Arguably speaking, the presence of counterfeit drugs in developing nations will continue to be exacerbated by the ease with which drugs are purchased on the Internet (Chaves, 2008-2009).

Second, "counterfeiting and piracy represent serious problems for all Latin American countries (McDermott, 2008)," yet producers and distributors of counterfeit or diverted pharmaceuticals often act with such impunity that they make a mockery of the justice systems currently in place. A failure of the regulatory system is to blame. As mentioned earlier, FTAs tightened IP standards for pharmaceutical products. However, a tightening of regulatory standards did not follow suit, and the result is a significant disparity in enforcement across countries in the region. One would assume uniformity to be a natural progression following IP improvements, but problems with FTAs have led to a situation where insufficient regulatory systems and ineffective government enforcement have resulted in the inability to control the type and quality of pharmaceuticals entering the market (Chaves, 2008-2009). Moreover, the struggle with weak regulatory structures has allowed for transnational counterfeit drug supply chains to develop, creating two related issues. One, given the complexity of the drug supply chain and the pains forgers take to conceal their origins, it is extremely difficult to pinpoint the hubs of international drug counterfeiting (Bate & Nugent, 2008). Two, as the counterfeiting business continues to operate on an international scale, it will become much more difficult to tackle the source of the problem and apprehend the parties involved (Jessop, 2012).

Adding to these problems is the level of importance assigned to counterfeit and diverted pharmaceuticals. Among Latin American countries, the prosecution of narcotics is much more likely because that class of drugs is viewed as a more serious threat to the international community. As such, judicial systems often times are simply unwilling to handle cases involving counterfeit pharmaceuticals. One reason for such apathy is that existing anti-counterfeiting legislation has proven largely ineffective, and the minor penalties that are imposed are an inadequate deterrent from the highly profitable business of counterfeit drug trade (Chaves, 2008-2009). This is the main reason why criminals

continue to evade arrest and prosecution. Resolving this weakness would most likely result in a greater number of arrests and prosecutions because, as the illicit drug trade has shown, uniformity in standards has proven successful in regulating both narcotics and psychotropic substances (Chaves, 2008-2009).

In response, the international community has made an effort to improve this situation, beginning with the World Health Organization's (WHO) 2006 establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). "At its core, IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe (World Health Organization)." Despite IMPACT's long-term objective of eradicating counterfeit pharmaceuticals, until 2011 no international treaty existed that imposed the same type of criminal penalties on people or entities engaging in the production or sale of counterfeit pharmaceuticals as those engaging in the illicit drug trade (Chaves, 2008-2009). This standardization came with the signing of the Anti-Counterfeiting Trade Agreement (ACTA). The agreement is a "groundbreaking initiative by key trading partners to strengthen the international legal framework for effectively combating global proliferation of commercial-scale counterfeiting and piracy (Executive Office of the President)." Although ACTA is a positive step in the fight against counterfeit pharmaceuticals for the greater international community, implications for Latin America are still limited strictly to Mexico, as it remains the only country in the region to have signed the agreement. Beyond ACTA, no other attempts at uniformity have been attempted.

Third, detection of counterfeit or diverted medicines is based primarily on a comparison between authentic and questioned products, involving detailed analysis of different elements in the existing packaging (Institute of Informatics - Universidade Federal do Rio Grande do Sul; Rio Grande do Sul Technical and Scienfical Division, Brazilian Federal Police; Department of Pharmacy - Universidade Federal do Rio Grande do Sul, 2012). Keeping in mind that the motivation for most counterfeiters is profits and not reliable products, counterfeiters are more inclined to perfect items such as packaging as opposed to contents, and consequently dangerous products are marketed to consumers as the real

thing (Bate & Nugent, 2008). Or in some cases, imitation products are not intended to resemble their corresponding authentic proprietary medical products, but they are presented as if they could generate the same effects. These products are presented as authentic medicines, but they may or may not contain the correct ingredients in fake packaging (Groupe de Chimie Analytique de Paris-Sud; Laboratories and Control Department, French Health Products Safety Agency, 2010)." Unfortunately, proper analysis to determine product integrity is largely expensive and time-consuming, and it often requires advanced technology, personnel with advanced training and the staffing necessary to complete any investigations. In developed countries, such requirements are challenging enough for authorities to manage. In Latin America, such requirements make it easier for counterfeiters to introduce products to the market because only a handful of countries are capable of committing the necessary resources to fund or promote programs aimed at detection of counterfeit pharmaceuticals.

As noted, detection of counterfeit pharmaceutical products is often difficult, so the numbers that are reported are often just the numbers reflecting actual seizures, arrests or reports of adverse reactions among consumers. On the consumer side, one explanation for poor detection is the level of education within a country. Sadly, many "consumers in developing nations lack adequate knowledge to distinguish a genuine drug from its counterfeit reproduction (Chaves, 2008-2009)." This is especially true of impoverished areas where limited education levels may result in public credulity and over-reliance on perceived levels of expertise bestowed upon authority figures (medical personnel included); residents in these areas are generally more willing to accept determinations of product integrity without question.

The consequence in these cases, unfortunately, is that the people often die or become ill when consuming these types of products. On a global scale, the death toll is high with as many as one million deaths per year, the majority of which occur in the developing world; though, increasing death tolls are now being seen in wealthy countries as well (Bate & Nugent, 2008). In addition to death or illness, sometimes the condition of individuals who consume counterfeits deteriorates due to increased resistance to actual medicines. The main reason for this is that counterfeit medicines are not produced under

Good Manufacturing Practices standards, so they often contain little or no active pharmaceutical ingredient (API)—the component necessary for products to be effective. When patients consume products with incorrect API dosages, diseases mutate, develop resistances to legitimate API and become even more difficult to treat. Furthermore, because counterfeit pharmaceuticals are often sold fraudulently, different qualities of counterfeits may be found at illegal markets or in OLPs; imitations may range from extremely toxic substances to inactive preparations (Groupe de Chimie Analytique de Paris-Sud; Laboratories and Control Department, French Health Products Safety Agency, 2010), so adverse patient reactions to counterfeit pharmaceutical products may range from a mild nausea to death.

Fourth, the changing political, economic and regulatory landscapes of Latin America have created significant challenges for IPR over the past decade. For this reason, the pharmaceutical industry established an almost universal intellectual property system with relatively high minimum standards. As part of this system, industrialized countries with an innovative pharmaceutical industry have usually applied high IP standards, such as the 20-year mandate, as a way to provide incentives to innovators (Gonzalez, 2008). Given the high costs associated with research and development of branded pharmaceutical products, companies in the industry use IP protections as a means to secure returns on investments. Although IP protections do help generate large revenues for pharmaceutical companies, developing nations have continuously claimed that the process of strengthening the rules on IPR undermines public health (Bernieri, 2006). Despite aggressive efforts, motions to rescind some of the IP restrictions have not been successful.

One explanation for this is that IP, "as an intangible asset, is included in some agreements under the definition of investment (Bernieri, 2006)." Whether one agrees or disagrees with this statement is irrelevant. What matters is that as witnesses to the debate, criminal organizations have now gained a stronger appreciation for IP as an extremely valuable commodity that can be traded or sold. Evidence of this may be the results of law enforcement testing on seized products showing that some counterfeit drugs are simply good copies of brand-name pharmaceuticals that breach IPR, yet are not inherently

dangerous due to their chemical proximity to legitimate products (Bate & Nugent, 2008); usually this pertains to longstanding products or products more commonly used to treat minor health conditions. However, of great concern for consumers is the alarmingly increasing trend of counterfeiters moving into far more life-threatening pharmacology, manufacturing drugs used to treat cancer, HIV/AIDS and serious heart conditions (Bate & Nugent, 2008). This bold transition to more complicated product lines is indicative of technical advancement and sophistication made capable only by possession of trade secrets and sensitive product knowledge; it is also indicative long-term, high-value revenue streams that will provide significant incentive for criminals to operate for decades as these chronic conditions are unlikely to be cured in the near future. If all of this is true, then the threat of IP theft is now credible and consistent with advanced counterfeiting capabilities that pose a real danger to consumers while simultaneously damaging the reputation of companies in the industry.

Fifth, global health's profit-making investment opportunities have been implicitly sanctioned by the WHO's 2000-2002 Commission on Macroeconomics and Health as a means of enhancing economic productivity and amassing private profits (Birn, 2011). Although not ideal, as counterfeiting organizations compete for market share, opportunities for diversification of criminal portfolios are becoming more attractive due to the increasing costs associated with counterfeiting. Interestingly enough, "life cycle management is now one of the hottest issues in the brand industry (Class, 2005)." While pharmaceutical companies focus on ways to repurpose branded products, criminal organizations are focusing their attention on ways to intercept products en route to customer locations or destined for incineration. This is purely a matter of economic incentives in that the risks associated with cargo theft and product diversion are much lower than the risks associated with counterfeiting, and the financial gains of cargo theft are much greater because manufacturing costs are not applicable. Furthermore, parallel trading is not always illegal in portions of Latin America, and this adds to the allure of diversion.

Parallel trade refers "to the option of importing a patented product that has been placed on markets both abroad and domestically, but is sold more cheaply elsewhere (Bernieri,

2006).” If a criminal organization steals cargo containing branded products in one country and diverts it for resale in another country, the potential for lucrative profits is greater for parallel products than for counterfeit products because no upfront expenses for labor, machinery or materials are incurred; legitimate pharmaceutical manufacturers bear all the costs of production. Furthermore, parallel trading of diverted products allows the governments of developing countries to save money by legally purchasing imported patented drugs that had also been approved for domestic sale (Bernieri, 2006), only at much lower prices. Unfortunately, as long as this situation exists, diversion will always be an issue for the region.

Having reviewed the history of the pharmaceutical industry in Latin America, one can understand how need and opportunity are the underlying reasons for the main security threats to the industry.

VI. Conclusion

Due to several regional challenges, affordable access to healthcare is not always a viable option for the citizens of Latin American, even in cases where citizens maintain private health insurance, because of the high cost for some pharmaceutical products. Thus, gaining access to essential medicines is even more challenging for citizens of a marginalized class who often lack the resources to afford health insurance and must pay out-of-pocket expenses or rely on government assistance for medical coverage. This situation is common throughout the region, and unfortunately it fosters a climate in which the *need* for treatment breeds a situation filled with *opportunities* for exploitation for financial gain. Understanding the implications of this lack of access scenario, this research aimed to identify the main security threats to the pharmaceutical industry in Latin America. In order to accomplish this, a five-step approach was used.

Step 1 entailed the use of three management tools and the proposed model to analyze different areas of the Latin American pharmaceutical industry. A PESTEL analysis identified characteristics unique to the region. A Porter’s 5 Forces analysis identified the influential forces at work in the Latin American pharmaceutical market. A SWOT analysis treated companies in the industry as a single entity in order identify weaknesses

and possible threats. Upon completion of each analysis, the results were scanned to identify vulnerabilities that could possibly expose the pharmaceutical industry to risk. These vulnerabilities were then processed methodically through the derived model from the literature review in order to generate a list of prosed threats to the industry. Step 2 entailed a series of interviews with security professionals who could provide real-time knowledge of ongoing and emerging threats. Step 3 applied theoretical concepts of affect and bias to help explain some of the answers provided in the interview process. Step 4 entailed a historical analysis of the past three decades of pharmaceuticals in Latin America. In addition, the historical analysis provides insight as to how the underlying factors of need and opportunity help to promote the element of threat. Step 5 entailed a review of modern trends and threats to demonstrate how they impact criminality.

The results of this research confirmed that the threat of counterfeit and diverted pharmaceuticals and the threat of criminal organizations continuing to operate are, in fact, credible threats to the pharmaceutical industry. Due to high pharmaceutical prices and an unmet demand for access to essential medicines among the citizens of Latin America, the opportunity to satisfy this demand for financial gain is the impetus for counterfeiters to enter the market. Moreover, lack of government attention, poor policing and weak punishment and enforcement standards present criminal organizations with every incentive possible to continue to operate with impunity since deterrents are not harsh enough to modify behavior.

The threat of IPR violation and IP theft was not validated as a security threat to the industry. Two possible explanations were provided. First, a misidentification or improper cataloguing of reported areas may be to blame. Because of the rigid focus of enforcement operations as a means to stop and prevent counterfeit and diverted pharmaceuticals from entering the region, technological advancements and increased sophistication in the types and qualities of counterfeit products seized may be dismissed and subsequently classified as a general counterfeit without consideration that the advanced products may be the result of IP theft. Second, a lack of awareness and shortage of communication may also be partly to blame. Because of how valuable IP and trade secret information are, there is a strong possibility that only critical stakeholders are fully aware of research and

development projects for innovative drugs. With authorities not knowing that certain projects are underway, there is no way for them to report incidents of IP loss when they do not even know what constitutes IP. In addition, in some Latin American countries, security forces are not to be trusted. Given the serious financial blow that can result from IP loss, critical stakeholders are highly unlikely to share IP information with the authorities since the temptation to sell information to competitors could lead to an unauthorized disclosure of sensitive information. Both situations explain why the threat to IP was not validated.

Interviews with industry professionals resulted in a threat that was not identified or proposed in any of the tools, models or analyses. The threat to personnel security weighed on the minds of the interviewees, at least enough to receive significant mention as part of the answer for Question 1 of the interview. However, unlike the threat of counterfeit or diverted products, the threat to personnel security was not classified as one of the most important threats in the region. Affect and bias are attributable to identification of the threat, but review of the wider implications and impact may have contributed to the threat being downgraded to the level of secondary concern.

Thus, the end result of this research is that counterfeit and diverted pharmaceuticals present a credible threat to the industry in Latin America. The need for wider access to medicine, coupled with financial motivations and weak enforcement standards, directly result in the presence of criminal organizations specializing in these two areas as a means to generate considerable revenue. Moreover, existing punishments, for the most part, are extremely weak and criminals will continue to act with blatant disregard of the law as a result since there is no incentive to change behavior. Furthermore, even if enforcement standards are improved, the continued presence of a lack of access and the high price for pharmaceutical products will continue to undermine any positive gains in the fight against these threats.

Limitations in this research include a small sampling of potential interviewees. Although efforts were made to meet with additional industry experts, including several high-level executives, scheduling conflicts and personnel reassignments consistently prevented any

opportunity to discuss the project. Although the panel of industry professionals assembled for this research are representative of the entire Latin American region, additional viewpoints would have lent more credence to the findings presented in this research, especially since the other potential interviewees are more focused on the business side of the industry as opposed to the security side of the industry. Another limitation is the nature of this research. Despite the fact that access to the industry's raw data and situational reports was granted, restrictions dictating what material could be disclosed in this research were heavily enforced. As such, although a significant amount of useful, available research material was studied, processed and catalogued as part of this project, nearly all of it had to be excluded in order to preserve longstanding information-sharing relationships between stakeholders.

Based on the findings of this research, it would be extremely interesting to explore the counterfeit and diversion problem from an ego and vanity perspective since the expressed need is not one of medical necessity, but one of behavior and the need to maintain virility and an attractive body image. Another interesting study would be to build on this research in the future with the incorporation of decision-making. Having identified the threats is one important step for companies in the industry, but using the information to develop decision-making strategies aimed at risk mitigation and risk management would prove extremely useful.

Appendix A: Interviews with Security Professionals

Security Professional #1 (SP1, 2013)

- Question 1: Piracy, product theft (internal robberies, cargo thefts) and security for the sales force when traveling by car.
- Question 2: Cargo theft and security for the sales force because despite the internal security measures that the pharmaceutical industry could perform, personnel are exposed to high rates of criminality on roads and in unsecure cities where criminal gangs operate.
- Question 3: Government policies to improve the security environment have had the opposite effect and have actually led to overall deterioration and increased violence between criminal gangs jockeying for power. A possible economic crisis in the future could also contribute to an increase in the presence of these threats.
- Question 4: Such threats primarily possess regional and specific country characteristics. The overall security environment will hardly change in the near future. Lack of education, lack of employment opportunities, criminal impunity and poor law enforcement contribute to this problem. A transnational component is that often criminals are better armed and supplied than law enforcement authorities due to the ease of acquiring weapons that have been smuggled through the black market.

Security Professional #2 (SP2, 2013)

- Question 1: Counterfeiting a parallel trade of diverted products are the greatest threats to the region. Well, let me restate that statement—in certain parts of the region that is the case. In other parts of the region the greatest threats relate to personnel security and the risk to outside sales forces.
- Question 2: As mentioned earlier, all three of the threats identified are significant, and I do not know whether any one in particular is of greater importance because

the region is so divers. But if I think about it in terms of impact to the industry I would say counterfeits and parallel trading of diverted products because of wider implications to the region. Barring financial loss and other impacts to the industry, I see these as the greatest concerns because of the dangers they pose for public health. It is not about branding or market share, it is strictly a public health issue because without any kind of control on parallel trading, governments who condone this type of activity are endangering people.

- Question 3: The problems in the region are primarily demand driven. In some cases, yes there are a lot of access issues in that end users are looking for cheaper products. In other cases though, the governments are the problem because they do not see issues with parallel trading because they have a need to provide healthcare for people and constantly look for the lowest-priced products to purchase. On the other side, profits are definitely a motivating factor for criminals to operate.

- Question 4: Yes, I would say that these threats have transnational components. Although counterfeits can be produced internally, a lot are not. Diverted products destined for parallel trade are definitely transnational because products from other parts of the world are winding up in the region. What is also of concern is that some established criminal organizations in one part of the region are now diversifying from traditional lines of operation to become involved in diversion that affects another part of the region.

Security Professional #3 (SP3, 2013)

- Question 1: There are two significant threats to the region—counterfeit pharmaceuticals and diverted cargo that is moving across borders to be sold in another country.

- Question 2: Neither one of these is more serious than the other. Both are big concerns because of the problems they cause for people who take them. They also help to expand the power of criminal gangs because as long as people need medicines there will always be a market to serve.

- Question 3: Money is the main reason. Criminals know they can make a lot of money with counterfeit pharmaceuticals because they know the police will do nothing.

- Question 4: Yes, with diverted cargo there is a transnational element. Usually the diverted cargo that is seen is destined for another use, such as another country or a public health program. Counterfeits are often locally produced and distributed, but there are some instances where they end up in other countries, but this is not normal.

Security Professional #4 (SP4, 2013)

- Question 1: The government controls almost all manufacturing in the country, but there is an overall lack of control for our industry. However, challenges remain because government still controls revenues and remittances to parent companies. In addition health authorities are also under heavy government influence, so there are restrictions on the types and quantities of products that can be imported. Moreover, because the manufacturing capabilities in the country cannot meet current demand, there are some access issues that need to be resolved, especially with current controls. Oil prices also pose a long-term threat to the industry because industry revenues are redistributed to fund public health programs.

- Question 2: Import substitution to supplement domestic manufacturing, primarily with generics, is a problem. However, this is not a threat for the near-term or short-term.

- Question 3: Lack of access is a possible cause, but another cause could be the issues we have with porous borders that facilitate smuggling. The current border situation is not the best, and there is a problem with counterfeits entering the country. Adding to that problem is the fact that there are no laws penalizing counterfeiters, so that means that criminals can do whatever they want knowing there is no risk of being prosecuted.

- Question 4: Yes, in terms of counterfeiters there have not been any real reports of Chinese counterfeit products entering the country. However, counterfeits are being produced in neighboring countries and are being smuggled across borders. Another transnational threat is diversion of products from other countries. This primarily occurs in neighboring countries where the price per dosage is extremely low. People are crossing borders and purchasing diverted products at a low price only to import them for resale at prices that are above cost, but still significantly lower than the price per dosage that is offered in country. One reason for this is the capability of our manufacturing sector, which I already addressed. The second reason is that the potential for profits is extremely high.

Security Professional #5 (SP5, 2013)

- Question 1: Cargo theft and counterfeit pharmaceuticals are the biggest threats to the industry; the majority of the counterfeits we see come from neighboring countries. However, some of the counterfeits that are seized have reportedly come from China, but these are isolated cases. The threat of counterfeits is a serious problem for two reasons. First, there is a definitely a lack of enforcement for this type of crime because at the border, the government pays closer attention to other types of smuggling. For example, one huge concern for the government is the influx of weapons coming into the country across the border because these weapons ultimately end up in the hands of criminal organizations. Security operations therefore tend to overlook pharmaceuticals. Second, the government in the country where the majority of imported counterfeits are produced appears rather apathetic in enforcing any standards or punishment because whether willing or unwilling, the country benefits from the revenues generated from criminal activity. Enforcement standards for us, on the other hand, are somewhat stringent with penalties averaging 15 years in prison.

- Question 2: Both threats are extremely complicated, but counterfeits are definitely a bigger threat because of the coordination required with law enforcement authorities and also because of how widespread the threat is. Now, cargo theft is

not to be discounted. It is serious, and factors like road infrastructure complicate the problem. However, in terms of which threat requires greater attention, it is definitely counterfeit.

- Question 3: The counterfeit issue is primarily profit motivated, but here is the reason why. The country has an ego problem. People are very vain and concerned with self-image and health, so the majority of counterfeits that are seized are lifestyle drugs, such as steroids and erectile dysfunction drugs.

- Question 4: Yes, the transnational threat mentioned earlier is the biggest concern, although there are some other countries of minor involvement.

Security Professional #6 (SP6, 2013)

- Question 1: There are a lot of risks to personnel, such as risks to the sales force, but more important are the risks associated with social movements and direct action, which are more prevalent here than in other part of Latin America. Specifically, social movements with political undertones, union or labor-related undertones and human rights undertones and animal rights activism are of concern.

- Question 2: There is also threat of cargo theft, and both freight and air cargo shipments are affected. Counterfeits are also an increasing trend given our proximity to a troublesome neighboring country. In addition to the other threats, counterfeits are a big concern.

- Question 3: With regard to cargo theft and counterfeits, a lot of that has to do with the industry in general not being able to reach underserved populations. As a result, criminal gangs have expanded operations into these underserved communities to try to exploit the demand for medicines. But this type of crime is seen mostly in areas that are either densely populated and marginalized, or somewhat remote and sparsely populated. A lot of it also has to do with education levels too in that people just do not know any better, so they consume whatever

products are available. Enforcement is also weak in this part of the region. Although laws are starting to change, punishment standards are a joke, and criminals know this. Crimes such as weapons smuggling carry heavy penalties, but counterfeiting is viewed as a minor crime for which there is little penalty. There is no deterrent in this case.

- Question 4: With the counterfeiting issue there is definitely a transnational component. However, one concern given the current economic and political situation is a policy shift that drives imports down and attempts to build the domestic manufacturing sector. Or a decline of imports in general that is not policy driven. Either way, there is a huge technology gap in country, so if imports decline it may be a hindrance for growth.

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