From NCIIA E-Team to Lifesaving Device:
A Case Study of Innovation and Entrepreneurship

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Abstract: This paper describes a case study of innovation and entrepreneurship. It is based on the evolving story of an idea that became a product and the basis for a company. Evan and Eric Edwards developed a greatly improved method for delivering epinephrine to those suffering from severe allergies and then spent over a decade learning how to get a product on the market, finally succeeding in January 2013. In this case study, students are asked to find their own solutions to the challenges faced by the inventors as they refined their design and created a company; students then learn what the inventors did, and compare what actually happened to what they thought ought to have happened. From this case, students learn lessons that better prepare them to be entrepreneurs.

1. The Nature of Cases and the Case Method

A case study is a narrative account of a situation, problem, or series of events. In business schools, cases frequently describe critical decision points in the history of a product or company. In engineering, cases may provide an account of a technical problem, design challenge, or ethical issue. Cases present problems to be solved and decisions to be made. At critical junctures, multiple choices are available; there is no obvious solution. Which answer is "best" depends on the relative importance one assigns to various criteria. Cases are usually derived from actual experience, and reflect the concerns of practicing engineers and “real world” decision-makers.

The case method is widely used in graduate business schools, most notably Harvard Business School and the Darden School at the University of Virginia (UVA). Cases are also prevalent in medical and legal education. There have been several case development projects for engineering education, dating from the early 1960s at Stanford. The American Society for Engineering Education maintained a case library for many years, and eventually passed it on to Rose-Hulman Institute of Technology.

An introduction to the use of cases in engineering is provided by Fitzgerald (1995). Richards et al. (1995) review the use of cases and the case method in business and engineering education. Petroski (1991, 1994) presents background material for a number of cases on engineering design; Gorman et al. (2000) provide cases involving ethical issues; and Aldridge and Swamidass (1996) and Raju and Sankar (1999) have cases that require detailed analysis at the intersection of technology, management and public policy.

The best sources on how to teach with cases are the books by Christensen (1989) and Bruner (2003). The case method promotes active learning and the ability to deal with ambiguous situations and open-ended problems (Meyers & Jones, 1993). It requires deeper levels of engagement, thought, and analysis than traditional classroom practices (lectures) and activities (problem solving). Cases help provide a context for the application of knowledge and techniques from engineering and industry, and

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highlight the fact that, in a corporation, technical work occurs in the context of business, political and cultural concerns.

This study describes an entrepreneurial journey that started in a class on invention and design at UVA (Richards et al., 1995; Gorman et al., 1995) and culminated, over a decade later, in a successful company (Intelliject, now Kaléo) and a life-saving product (Auvi-Q/Allerject). The case is presented in nine segments; each section culminates in a decision point. After reading each section, the students are presented with a set of questions about what to do next. These questions appear in Table 1 at the end of the narrative (page 10). The class discussion results in a decision about the best path forward. Then this decision is compared to what the Edwards actually did at each point.

2. The Case of Intelliject: The bumps are the road - Evan Edwards

2.1 Can a Student Also Be an Entrepreneur?

Evan and Eric Edwards are twin brothers who have suffered their whole lives from severe allergies to common food items such as peanuts, tree nuts, seafood, and eggs. Exposure to or accidental ingestion of any of these foods can happen when it is least expected. Evan learned this the hard way at a young age, while playing at a friend’s house; he ate what was promised to be a “fake peanut.” Evan began to have an allergic reaction almost immediately; he suffered what is called anaphylaxis. Common symptoms of this include rashes, swelling of the throat, and low blood pressure (“Allergies and Anaphylaxis,” 2014). Fortunately, Evan’s friend’s father was also the twins’ doctor so he was treated immediately and all turned out well. This incident taught both boys an important lesson; they would always have to carry an EpiPen with them in case of exposure to a potentially fatal allergen. The need to carry an EpiPen is quite common; epinephrine was a $700 million market at the beginning of 2013 and that value grows by about 23% each year (Edwards, 2013). There are an estimated fifteen million Americans with food allergies and the rate of children with these allergies has increased by roughly 50% between 1997 and 2011 (“Food Allergy Facts,” 2014).

The EpiPen (see Figure 1) is currently the most popular epinephrine auto-injector on the market, but it is far from a perfect device. It is about the size of a large whiteboard marker, and many allergic individuals, including the Edwards twins, find it to be an inconvenient item to carry. There is also the problem of design ambiguity. The EpiPen is designed so that the user must remove a safety cap from one end of the device and then a needle comes out from the other end when it is pressed against the patient’s leg. This may cause confusion, and in fact there have been cases where untrained users have accidentally injected themselves in the thumb rather than deliver life-saving medication to the patient (Guerlain, personal interview, 2013).

Figure 1. Most current design of EpiPen
In the summer of 1998, as they were on their way to the airport for a European vacation, Evan and Eric realized that neither of them had packed an EpiPen. Fortunately, their mother had packed a spare. But the potential close call made the boys realize the need for a more compact epinephrine auto-injector that would be easier to carry at all times. They resolved to create an improved device, one with a less unwieldy container and a less confusing design.

In the fall of 1998, Evan was starting in the School of Engineering and Applied Science at the University of Virginia and Eric was starting at Virginia Commonwealth University (VCU) as a part of their Guaranteed Medical School program. Evan and Eric came up with a plan so that they could learn all they needed to know in order to design their own product, an epinephrine auto-injector about the size of a credit card cell phone. Evan went into mechanical engineering and Eric majored in biology/pre-medicine. Two years later, in the spring of 2000, Evan took a class taught by Professors Michael Gorman and Larry Richards called “Invention and Design.” In this class, students of various engineering disciplines worked in teams to develop a new product. Evan went to Drs. Gorman and Richards early in the semester with his idea for a new drug delivery device. They saw that Edwards understood, from a personal perspective, why a credit card cell-phone-sized device could be transformative for users, and they could also see he was motivated. The professors were willing to help Edwards try to obtain funding, but he would have to write the proposal himself. Fitting the development of a new and revolutionary product into his already busy student schedule would be a real challenge for Evan. Refer to Table 1, Decision Point 1.

2.2 NCIIA Funding

At the end of their second year, Evan and Eric applied for an Advanced Entrepreneurship Team (E-team) grant from the National Collegiate Inventors and Innovators Alliance (NCIIA) and were awarded $13,769 in the summer of 2000. The NCIIA works to promote innovation and entrepreneurship in higher education by providing students and teachers with the resources to engage in real-life technological ventures. The E-team grants, in particular, help to provide early-stage funding to young entrepreneurs with innovative ideas for new products and companies (NCIIA, 2014). The grant competition required the submission of a full business plan and budget as well as résumés and letters of recommendation from relevant experts. The E-team comprised Evan Edwards, Eric Edwards, and Professor Larry Richards. External mentors included Evan and Eric’s allergist as well as another MD, several Richmond business contacts, and Evan and Eric’s older brothers Byron and Jeffrey who served as business development advisors.

The E-team refined their concept, began calling the device EpiCard, and applied for a patent in August 2001, which was awarded to both Evan and Eric Edwards in 2003 (patent number 6,530,904). Evan and Eric were also able to have the first working prototype made at the Swanson Center at the University of Pittsburgh with combined support from the NCIIA, the National Institutes of Health, and Dr. Richard’s university contacts.

In 2001, Evan and Eric officially founded a company around their invention called Intelliject, Inc., using their family as the executive board. The boys’ father served as CEO and president. He had previously worked as Manager of Capacity Acquisition for Dominion Resources and so brought his knowledge of contracts to Intelliject, Inc. His wife, Mrs. Edwards, served as secretary of the board. Evan and Eric’s oldest brother, Byron, served as finance manager and their brother Jeff handled marketing. Both older brothers were also working separate full-time jobs. Other than family members, Intelliject, Inc. had the involvement of Mark Licata (President of Biotrack, a medical device consulting firm) and an independent advisor and investor. Evan cites the backing of his family as a major reason for why he and Eric had the courage and resources to pursue their idea in the first place.
In 2002, the E-team was honored at the NCIIA March Madness for the Mind held at the Smithsonian Institute in Washington, D.C. This high-profile event attracts a wide array of people and media. Evan spent all day at the convention showing off his prototype. The idea attracted the attention of many allergy sufferers as well as military representatives who saw the device as a potential asset on the battlefield. The support and enthusiasm from so many individuals filled Evan and the rest of the E-team with the confidence to more aggressively pursue their invention.

In May of 2002, Evan graduated with a bachelor’s degree in mechanical engineering. He now had a key decision to make. Refer to Table 1, Decision Point 2.

2.3 Could More Education Help with Entrepreneurship?

Instead of entering the workforce immediately, Evan decided to stay at UVA and pursue a master’s degree in systems engineering, working under Professor Gorman, who urged him to pick a thesis topic pertinent to Intelliject, Inc. and the EpiCard. In most cases, this would have been tricky to do; often the intellectual property developed by an individual while pursuing a degree is claimed by the sponsoring university, but Evan did not face this impediment. While still an undergraduate, Evan had obtained a letter from the provost for research stating that the university had no claim on any of his intellectual property. This gave him the freedom to pursue his dream while deepening his expertise with an advanced degree.

Evan chose to focus on human-factors engineering integrated into the FDA’s design control process and used the EpiCard as the basis for his research. This focus allowed him to continue working on the product that he was so passionate about; it also gave him both insights on how to further improve his design and important professional contacts that he could rely on in the future.

In the summer of 2003, Evan entered the UVA Darden Business Plan Competition and was one of four finalists. That success won him office space for the summer in the Darden incubator (a business panel of industry experts) and $2,500 in funding. The Darden competition usually involves only Darden students working with faculty members in order to commercialize ideas developed in their research labs. For a graduate student from engineering to be a finalist was a significant accomplishment.

Evan completed his masters of science degree in Systems Engineering in 2004. His thesis was entitled “The Development of Design Controls and Quality System Requirements for a Biomedical Start-Up Company Utilizing Human Factors Engineering.” This thesis allowed Evan to develop a strategy for doing the human-factors studies and simulated-use testing to ensure that EpiCard met or exceeded FDA requirements. Evan’s research also served as a foundation for an invitation to be a co-instructor of the Association for the Advancement of Medical Instrumentation human-factors workshop, a three-day course that is taught biannually to medical device manufacturers and pharmaceutical companies. Among the other instructors of the workshop was Ron Kaye, the Food and Drug Administration’s (FDA) human-factors team leader. For two years during graduate school, Evan co-taught the undergraduate Invention and Design class that he had previously taken at UVA and was also the head teaching assistant for the Washington internship program run by the Department of Technology, Communications, and Culture.

After graduating, Evan began working at Accenture in October 2004 and pursued his own company only on the side. This decision was motivated by the other events taking place in his life. Evan was now planning to get married and start a family. The financial security of a job with an established company was appealing because it would allow him to support his future family. However, his heart
was still with Intelliject, Inc. He would often get on conference calls with Intelliject’s contracted industrial design firm during his lunch breaks in order to keep his invention moving. Then in January 2005, after 3 months with Accenture, Evan decided to follow his passion completely and started full time with Intelliject, Inc. This decision was made with the full support of Evan’s parents and his fiancée; Evan was even able to live at home during this time so that all of his resources could be dedicated to the company that he and Eric were working so hard to build.

At the time, the young company was located at Virginia BioTechnology Research Park (VA Biotech Park) in Richmond, VA. The research park incorporated a think tank and an incubator program, Virginia Biosciences Development Center (VBDC), to help start-up businesses like Intelliject, Inc. get up and running. Young companies that want space in this incubator are required to go through a formal application process. Once accepted, a company finds that there are multiple types of facilities available for lease or sale.

Over the course of 2005, Intelliject, Inc. was constantly trying to raise money. The executive board, now including David Lohr (at that time, head of the VA Biotech Park VBDC and Intelliject, Inc.’s acting CFO), would pack up and go on road shows to attract investors. They would present the EpiCard and their company as a whole to as many potential investors as they could. Angel investors were wary of investing in the company because it was largely family-run and its board did not have all the expertise necessary to make the business successful. As a condition for seed money for their business, Evan and Eric were asked by an angel investor to replace their parents and brothers on the executive team with individuals who had more experience managing medical device companies. This would be a difficult thing for the twins to do. Their family had been generous with both time and money from the start and to simply oust them would place a strain on the family dynamic. Refer to Table 1, Decision Point 3.

2.4 Device or Drug?

After much consideration and advice from mentors and investors, the Edwards family decided to scale back the family involvement in the company and set out to hire an experienced team that could take the company to the next level. Intelliject, Inc. secured money from additional angel investors, and this gave them the funding to hire additional management with a focus on recruiting an experienced CEO.

In 2005, Intelliject, Inc. took its idea for an auto-injector to the FDA. When taking a new product to the FDA, companies must first learn from the FDA’s Office of Combination Products whether the product will be regulated as a drug or as a device. The team first thought that EpiCard would be regulated as a device. Obtaining 510k clearance for a new device with the FDA takes about 90 days and costs a few hundred thousand dollars. Obtaining the required FDA approval for a new drug is a much more involved process (Edwards, 2013). The drug approval process costs millions of dollars and takes years to accomplish, including clinical trials. The first phase of tests for a brand-new drug (Phase I) involves the use of rats or other similar animals, next come clinical studies with humans (Phases II and III), and finally simulated use testing with potential end users (Design Validation) (Guerlain, personal interview, 2013).

The EpiCard was taken to the FDA Office of Combination Products, from whom the team learned that, because of its new smaller container and different concentration of epinephrine, their auto-injector would be classified as a drug. Because the FDA had already approved epinephrine decades ago, as well as the EpiPen, Intelliject, Inc. could use the EpiPen as their reference listed drug (RLD) during testing and avoid the first two phases. Still, there would be many steps to take, including a clinical study with humans, and the young company would need to raise large amounts of capital.
Evan and Eric had to decide whether to keep going or not, now that the stakes were so much higher. At this point, the Edwards were about 25 years old and were thinking about getting married and starting families. Could these millions of dollars and this large amount of time be better spent on something else? Would their children have the same life-threatening allergies that they did and therefore require an epinephrine auto-injector too, facing similar challenges? Refer to Table 1, Decision Point 4.

2.5 Hiring a CEO

Evan and Eric decided to continue moving forward in pursuit of FDA approval for their “new drug,” citing their experiences as lifetime patients and the support of their parents, who understood the challenges of raising severely allergic children, as motivation. Now that Intelliject, Inc. was being viewed as a pharmaceutical company, they needed to learn how to develop the drug. The company hired various regulatory and drug development consultants in order to help them do this. In addition, the company reached out to various device development companies and contract manufacturers in order to optimize the design for manufacturability.

While seeking FDA approval for its epinephrine auto-injector, Intelliject, Inc. was still searching for a long-term CEO. In 2006, this search was in high gear and many candidates were being interviewed. Many, but not all, of these potential company leaders had strong ideas about where to relocate the company. Among the locations discussed by these potential leaders were the North Carolina’s Research Triangle Park, California, and New England. Evan and Eric were hesitant to move their company from Virginia, as they wanted to maximize the benefit to their home state as well as remain close to UVA and VCU, where they had received so much support early on. In addition, they believed that continuing in proximity to FDA and other key pharmaceutical “hubs” would prove beneficial in the future. But perhaps these potential CEOs had the right idea; they had experience and business contacts in other locations that could propel Intelliject, Inc. to a new level of success. Refer to Table 1, Decision Point 5.

2.6 Manufacturing the Auto-injector

After several interviews and careful deliberation, the twins along with other members of the Edwards family decided to hire Spencer Williamson as the new CEO of Intelliject, Inc. Williamson was a referral from a potential investor and had recently left a large medical device company. Spencer had a strong network already in place in Richmond and he was eager to return to Virginia’s capital. Most importantly, Spencer shared the culture, vision and values that the family believed to be crucial for building the “right” company. Evan and Eric wanted to build their company in Virginia, and Spencer was the man to help them accomplish their goals.

At this point, it became important to find a company to make Intelliject, Inc.’s new auto-injector and to prove that it could be manufactured at a reasonable price. The device had to be made in an industrial setting under strict design controls and manufacturing practices. When choosing a contract manufacturing organization (CMO), there were two main types of options. A company such as Intelliject, Inc. could choose to partner with a larger manufacturing company, one with many resources, relevant product experience, the ability to make assurances, and a low probability of folding. On the other hand, they could choose a smaller manufacturer where Intelliject, Inc. would be one of the largest, most important clients. Being the primary client of a smaller CMO could be beneficial because of the level of customer focus they would receive. Alternatively, a larger manufacturer offered security and recognition within the industry that a smaller competitor may not have been able to provide. Regardless of company size, new automation equipment would need to be
purchased in order to build their product. Most CMOs don’t have their own automation equipment to retrofit, so the expense of this large purchase was almost a guarantee. The main price differences came from contract prices and prices of materials. Contracting with a large CMO could cost up to ten times more initially, as such companies have a much larger overhead and the ability to charge for their reputation. But these large companies could also obtain the raw materials necessary for production at a much lower cost; they often buy in such large quantities due to the large number of devices they are producing that bulk discounts are common. Refer to Table 1, Decision Point 6.

2.7 Human-factors Expertise

Intelliject, Inc. decided to make a deal with a smaller contract manufacturer where the production of the auto-injector represented a large portion of business. This allowed the two companies to work quickly to develop and make necessary changes to the product as neither Intelliject, Inc. nor the contract manufacturer had an overly large administration to work through.

Over the next two years, Intelliject Inc. focused largely on implementing design controls on their auto-injector and on working with the CMO to design the product for manufacturing. The goal was to move from conceptual engineering work to producing clinical and pilot production batches, ultimately submitting their new drug application (NDA) to the FDA’s Center for Drug Evaluation and Research.

One particular challenge when finalizing the development of the auto-injector was the selection of key consultants for certain activities. In particular, the team needed to ensure a robust human-factors engineering program that included simulated use testing. Typically, a consulting firm is hired to do this type of work. The consulting firm, in this case, would take possession of the product in question, provide design recommendations to optimize it for the user population, and test the product. The owner of the product is expected to follow the advice given by the consultant. The consulting firm would have relevant experience and its advice should thus be trusted; however, they may not be the true experts on the product.

Because Evan’s graduate work involved learning human-factors engineering and the implementation of design controls that would allow the auto-injector to be used effectively by its target demographic, Evan had worked with Dr. Stephanie Guerlain, a professor in the Systems Engineering at UVA. Stephanie had extensive experience with human-factors research and had previously worked to have research approved through the institutional review board at UVA. The process is not the same as obtaining FDA approval for a medical product, but there are enough similarities that Stephanie could be a guide if Evan employed her help for Intelliject Inc.’s human-factors program. Working with Stephanie would also allow Evan and the Intelliject Inc. team to take a more hands-on approach to their device. Evan already had a relationship with Dr. Guerlain, so collaboration was an option, one more cost effective than some of the other human-factors consultants that the team had explored. The research done by Dr. Guerlain would also be much more in-depth, addressing more than the topics simply required by the FDA. Dr. Guerlain would help to make changes and improvements to the product that would likely benefit Intelliject Inc. when the product went to market.

Other human-factors consultants had much more direct experience with the FDA submission process. Though these consultants are more likely to simply walk their customers through the approval process, their human-factors research would be much less in-depth and it would be unlikely that changes and improvements would be made to the product during this process. The method employed by consultants would mean that research on the auto-injector may be able to be presented to the FDA much sooner, and Evan and Eric had a strong desire to get their product to market. Refer to Table 1, Decision Point 7.
2.8 What Size Pharmaceutical Company Should Edwards Partner With?

Intelliject Inc. decided to hire Dr. Guerlain for the human-factors work and usability testing. This collaboration gave Evan the opportunity to learn even more about the FDA approval process and the simulated use testing necessary to create an effective drug delivery device. The epinephrine auto-injector is an interesting object from a human-factors perspective; an epinephrine auto-injector needs to be able to be used by any person, in any environment, and in a very stressful use scenario. This means that it must be easy to use, even by a person under the mental duress of an allergic emergency, and so must come with clear instructions. In order to meet this requirement, the team conducted significant research with various stakeholders, including parents of allergic children, adults, laypersons, nurses, and physicians. The product requirements were defined—including the focus on a small, credit-card-sized form for the device, a retractable needle system, a unique voice prompt system to provide audible instructions for use and visual aids to assist the user through the injection process, and a level of simplicity much like that of an automated external defibrillator (AED)—to make use possible for both layperson and caregiver. From here, multiple usability tests were conducted with multiple demographics including different age groups, people with no prior experience, people with limited training, and nurses. All findings from these studies were submitted to the FDA as part of the review process.

In 2009, the Company was continuing to present their product to various pharmaceutical companies that had the potential to further develop, manufacture, and/or commercialize the asset. They presented to small, medium and large companies, with each having pros and cons. The small companies would be able to make this asset a priority “in their bag” that they presented to doctors and had the ability to have close collaboration with Intelliject Inc. However, the small companies may not have the financial resources and geographic footprint to effectively spread the product nationally (or internationally). A larger company as a partner would clearly be able to commercialize the asset, present an attractive financial deal, and distribute it on a larger scale; however, such an organization may not view the product as important in their overall portfolio and it may not strongly impact their bottom line. In addition, Intelliject Inc. had to wrestle with exactly what type of deal was ideal for the future. Should they allow the pharmaceutical company to market anywhere in the world where the product had been approved, or only in a limited area? If Intelliject Inc. decided to use its auto-injector for medicines other than epinephrine in the future, should this partner have rights to those as well? Currently Intelliject Inc. was only trying to have their device licensed in North America, but what if they decided to expand to a more global market? Refer to Table 1, Decision Point 8.

2.9 You Know You Are Successful When You Get Sued

Intelliject struck a deal with Sanofi, the fourth-largest pharmaceutical company by prescription sales in the world. Sanofi would be in charge of the manufacturing and commercialization of Intelliject Inc.’s auto-injector, but only for epinephrine in North America. This partnership with a large pharmaceutical company complemented Intelliject Inc.’s existing partnership with a smaller manufacturer nicely, and Sanofi’s large sales force created the opportunity to reach as many patients as possible throughout North America. This broad reach would in turn optimize the potential for saving the most lives. Intelliject Inc. was responsible for finalizing development and obtaining final FDA approval. The capital obtained from Intelliject Inc.’s deal with Sanofi made it possible for the emerging company to successfully bring their new product to the ever-growing epinephrine auto-injector market.

Intelliject, Inc.’s partnership with Sanofi proved especially beneficial in January 2011 when King Pharmaceuticals, the makers of EpiPen, sued Intelliject Inc. over alleged patent infringement. Sanofi had paid Intelliject Inc. 25 million dollars upon entering their contract and that money supported
Intelliject Inc. to continue operations and support litigation. The lawsuit was settled in February of 2012 before it went to court, unfortunately delaying Intelliject Inc.’s entrance into the market. The FDA would only grant tentative approval to Intelliject Inc.’s auto-injector until the lawsuit was resolved and legal fees could easily have forced Intelliject Inc. to fold had they not had the backing and support of Sanofi. In 2012, after the lawsuit had been settled, the FDA did grant final approval to Intelliject Inc.’s auto-injector, now called the Auvi-Q in America and Allerject in Canada. This lawsuit also left Intelliject Inc. in a stronger position than they were in before. They proved to the pharmaceutical world that they wouldn’t be wiped away easily and this likely garnered new respect from competitors and possible future partners.

In January of 2013, Auvi-Q/Allerject became available in both the United States and Canada is are already saving lives (Honodel, 2013). Refer to Table 1, Decision Point 9.

![Figure 2. Auvi-Q 0.15mg and Auvi-Q 0.3mg](image)

3. Notes

The authors are grateful to Evan Edwards for information contained in this case study, but this paper does not necessarily reflect the views or positions of Intelliject, Inc. As of January 6, 2014 Intelliject, Inc. has changed their name to Kaléo (a Greek word for “a calling” or “purpose”), which they believe is a better reflection of the company’s potential.

All material is based on research into publicly available documents and interviews with participants in the creation of the Auvi-Q/Allerject. Gorman and Richards both worked with Evan Edwards as an undergraduate and a graduate student at UVA, so some material comes from their experience as well. Evan Edwards (Kaléo Vice President of Product Development) was interviewed by Esther Klinger on June 12, 2013, and again on November 21, 2013.

This case was piloted in one of Professor Gorman’s fourth year Engineering and Society courses at UVA, and the current draft reflects feedback from the students designed to improve the case—the authors thank them for their input. Those interested in using the case should contact Michael Gorman (meg3cstar@gmail.com) for teaching notes and revisions to the case materials. Larry Richards may be contacted at lgr@virginia.edu.
Table 1. Discussion Questions for the Decision Points for the Edwards Case

<table>
<thead>
<tr>
<th>Decision Point</th>
<th>Discussion questions</th>
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<tbody>
<tr>
<td>1</td>
<td>Should Edwards pursue this invention idea on top of all of his other commitments? How can he manage to do this while in school? What entrepreneurial support is available at your university?</td>
</tr>
<tr>
<td>2</td>
<td>Where should Evan go from here? Should he get an advanced degree? Should he go to work at an engineering company and begin earning money for his future? Either of these options would mean pursuing Intelliject, Inc. only on the side. Should he instead focus completely on his invention?</td>
</tr>
<tr>
<td>3</td>
<td>Do you change the involvement of the family? Is this family involvement tied to the values of the company?</td>
</tr>
<tr>
<td>4</td>
<td>How do you progress after discovering the magnitude of the project? Do you continue to pursue FDA approval of the auto-injector? Do you look for a new project? Is there another potential course of action?</td>
</tr>
<tr>
<td>5</td>
<td>Do you allow your company to be moved to an ideal geographic location, relying on a CEO’s past experience and contacts to make Intelliject, Inc. successful?</td>
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<tr>
<td>6</td>
<td>Which size contract manufacturer do you choose? What are the benefits of a small, medium, or large contract manufacturer?</td>
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<tr>
<td>7</td>
<td>Do you hire a human-factors expert consulting firm and move directly toward FDA approval, or do you slow down and hire Dr. Guerlain, thereby allowing for more potential improvements with regard to human factors while still obtaining FDA approval? What is the opportunity cost associated with a delay?</td>
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<tr>
<td>8</td>
<td>What size of pharmaceutical partner should Intelliject Inc. choose? What territories will it cover and what medicines should be targeted as a part of the deal? How will this decision affect the company’s future? What are the pros and cons of your selected option?</td>
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<tr>
<td>9</td>
<td>Where do you take the company now? Do you focus on international expansion? Do you start developing a new product or products? Do you choose another option? What motivates this choice?</td>
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Table 2. Timeline of Key Events in the Intelliject Case

<table>
<thead>
<tr>
<th>Year</th>
<th>Key Events</th>
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<tbody>
<tr>
<td>2000</td>
<td>Evan proposes idea of drug delivery device to Gorman and Richards in invention and design course. Summer: Evan and Eric receive funding from the NCIIA. Aug: EpiCard provisional patent is filed.</td>
</tr>
<tr>
<td>2003</td>
<td>March: EpiCard patent is awarded.</td>
</tr>
<tr>
<td>2005</td>
<td>Intelliject, Inc. learns that their product will be classified as a drug.</td>
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<tr>
<td>2006</td>
<td>Intelliject, Inc. hires Spencer Williamson as CEO. Intelliject, Inc. begins working with a contract manufacturer (CMO).</td>
</tr>
<tr>
<td>2009</td>
<td>Nov: Intelliject, Inc. and Sanofi-Aventis enter into licensing agreement.</td>
</tr>
<tr>
<td>2011</td>
<td>Jan: King Pharmaceuticals sues Intelliject, Inc. over possible patent infringement.</td>
</tr>
<tr>
<td>2012</td>
<td>Feb: Lawsuit with King is settled.</td>
</tr>
<tr>
<td>2013</td>
<td>Auvi-Q/Allerject is released to market.</td>
</tr>
</tbody>
</table>

References


