

FROM NCIIA E-TEAM TO LIFESAVING DEVICE

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The authors are grateful to Evan Edwards for information contained in this case study, but this paper does not necessarily reflect views or positions of Intelliject, Inc. The authors take full responsibility for the content, including any errors that may be present.

ABSTRACT

This paper is organized in the form of a case study to be presented to students who make multiple decisions based on the evolving story of an idea that becomes a product and the basis for a company. Evan and Eric Edwards thought of a greatly improved method for delivering epinephrine to those suffering from allergies and then spent over a decade learning how to get it on the market, finally succeeding in January 2013. Students are asked to find their own solutions to the challenges that faced the inventors as they evolved their design and created a company; they then find out what the inventors did, and compare what actually happened to what they thought ought to have happened. From this case study, students learn lessons that better prepare them to be entrepreneurs.

"The bumps are the road" -- Evan Edwards

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 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, suffering from something called anaphylaxis. Common symptoms of anaphylaxis include rashes, swelling of the throat, and low blood pressure (WebMD 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 being born with these allergies has increased by roughly 50% between 1997 and 2011 (Food Allergy Research and Education n.d.).

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, after which a needle protrudes from the other end when 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 2013).



Figure 1. Most current EpiPen design. Source: <http://www.epipen.com/About-EpiPen/Overview>

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 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 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 cellphone-sized device could be transformative for users, and they could also see that he was motivated. The professors were willing to help Evan 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.

Student Decision Point 1: Should Evan Edwards pursue this invention idea on top of all of his other commitments? How can he manage to do this while in school?

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 n.d.). The grant competition required the submission of a full business plan and budget, as well as resumes and letters of recommendation from relevant experts. The E-Team was comprised of 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 # 6,530,904). Evan and Eric were also able to have the first working prototype made at the University of Pittsburgh's Swanson Center with combined support from the NCIIA, the National Institutes of Health, and Dr. Richard's university contacts.¹

In 2001, Evan and Eric officially founded a company around their invention called Intelliject, Inc., using their family as the executive board. Their father served as CEO and president. He had previously worked as Manager of Capacity Acquisition for Dominion Resources and brought his knowledge of contracts to Intelliject, Inc. Their mother 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 why he and Eric had the courage and

¹ Intelliject, Inc. does not wish to disclose the private sources of its funding at this time.

resources to pursue their idea in the first place. Family was important to the boys from the very beginning, and the strength of their family's support increased the twins' resolve to move forward and save lives with their revolutionary product as soon as possible.²

In 2002, the E-Team was honored at the NCIIA March Madness for the Mind event held at the Smithsonian Institute in Washington, DC. This high-profile event attracts a wide array of people and media. Evan spent all day at the convention demonstrating his prototype. The idea attracted the attention of many allergy sufferers, as well as military representatives who saw the device as a potential battlefield asset. The support and enthusiasm from so many individuals filled Evan and the rest of the E-Team with the confidence to pursue their invention more aggressively.

In May of 2002, Evan graduated with a bachelor's degree in mechanical engineering. He now had a key decision to make.

Student Decision Point 2: 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?

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

² See Appendix 1 for timeline.



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 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 Master 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 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 the University of Virginia, 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 as a side concern. 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 participate in conference calls with the Intelliject, Inc. industrial firm during his lunch breaks in order to keep his invention moving. Then in January 2005, after three months with Accenture, Evan decided to follow his passion completely and began to work 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 in Richmond, VA. The research park incorporated a think tank and an incubator program to help startup 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, there are multiple types of facilities available for lease or sale. Over the course of 2005, the company was constantly trying to raise money.

The executive board, now including David Lohr (at that time, head of the VA Biotech Park incubator and Intelliject, Inc.'s acting

CFO), would pack up and go on road shows to try and gain 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 they felt 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. Evan and Eric both cherished their family and they would never want to alienate their loved ones.

Student Decision Point 3: Do you change the involvement of the family? Is this family involvement tied to the values of the company?

Device or Drug?

After much consideration, The Edwards family decided to scale back the family involvement in the company and set out to hire an experienced team who 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 Food and Drug Administration (FDA). When taking a new product to the FDA, companies must first determine from the FDA's Office of Combination Products if the product would be regulated as a drug or as a device. The team first thought that it 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, as multiple phases of testing must be done, including clinical trials. The first phase of tests for a brand-new drug (Phase I) involves the use of rats or other similar animals, then come clinical studies with humans (Phases II and III), and finally simulated use testing with potential end users (Design Validation) (Guerlain 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 now that the stakes were so much higher. At this point, the twins 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 face similar challenges?

Student Decision Point 4: 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?

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 device 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 Research Triangle Park in North Carolina, 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.

Student Decision Point 5: 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?

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 add value to Virginia, and Spencer was the man to help them do just that.

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. They could also choose to partner with 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 might not be able to provide. Regardless of company size, new automation equipment would need to be purchased by Intelliject, Inc. 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.

Student Decision Point 6: Which size contract manufacturer do you choose? Is there another option not previously discussed?

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 Contract Manufacturing Organization (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, companies hire a consulting firm 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 abide by 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 department at UVA. Guerlain 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 Dr. Guerlain could be a guide if Evan employed her help for Intelliject, Inc.'s human factors program. Working with Dr. Guerlain 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 were 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 could be presented to the FDA much sooner, and Evan and Eric had a strong desire to get their product to market so they could begin saving lives.



Student Decision Point 7: Should Evan hire a human factors expert consulting firm, or hire Dr. Guerlain, thereby facilitating a much more collaborative approach for their human factors / usability testing?

What Size Pharmaceutical Company Should Edwards Partner With?

Intelliject, Inc. decided to hire Dr. Guerlain for their human factors work and usability testing. This collaborative option 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: it needs to be able to be used by **any** person, in **any** environment, and under 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, and a unique voice prompt system to provide audible instructions for use and visual aids to assist the user through the injection process, working at a level of simplicity much like that of an automated external defibrillator (AED) and thus making 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 continued 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 would have the ability to collaborate closely with Intelliject, Inc. However, the small companies might 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, would present an attractive financial deal, and could distribute it on a larger scale. However, such an organization might not view the product as important in their overall portfolio and it might 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?

Student Decision Point 8: 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?

You Know You are Successful When You Get Sued

Intelliject, Inc. 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 nicely complemented Intelliject, Inc.'s existing partnership with a smaller manufacturer, 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 allowed 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 had proven 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, the Auvi-Q™/Allerject™ became available in both the United States and Canada and are already saving lives (Honodel 2013).

Student Decision Point 9: 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?

Notes

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.

As of January 6, 2014, Intelliject, Inc. has changed their name to Kaléo (a Greek word for "a calling" or "purpose"), as they believe this new name is a better reflection of the company's potential.

This case was piloted in a section of one of Gorman's 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. The authors plan to create a teaching note for those at other institutions who want to use the case and would like more background information. Those interested in using the case should contact the second author for teaching notes and revisions to the case materials.

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Appendix 1: Timeline of Key Events

1998	June: Evan and Eric Edwards first conceive of the idea for an EpiCard.
2000	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.
2001	March: Intelliject, Inc. is formed.. July: EpiCard utility patent filed.
2002	March: Conceptual prototype created by John Swanson Center. March: E-Team presents at NCIIA's March Madness of the Mind.
2003	March: EpiCard patent is awarded.
2005	Intelliject, Inc. learns that their product will be classified as a device.
2006	Intelliject, Inc. hires Spencer Williamson as CEO. Intelliject, Inc. begins working with a contract manufacturer (CMO).
2007	Aug: Intelliject, Inc. begins working with Dr. Guerlain on human factors.
2009	Nov: Intelliject, Inc. and Sanofi-Aventis enter into licensing agreement.
2011	Jan: King Pharmaceuticals sues Intelliject, Inc. over possible patent infringement.
2012	Feb: Lawsuit with King is settled.
2013	Auvi-Q/Allerject is released to market.