

# GLOBAL HEALTH

## Innovation Insight Series



Photo courtesy of 3<sup>rd</sup> Stone Design

*A nurse in Swaziland learns to use the DoseRight device*

## DOSERIGHT I: Moving Out of the Lab

RICE 360° INSTITUTE FOR  
GLOBAL HEALTH TECHNOLOGIES

RICE UNIVERSITY  
TEXAS, USA

3<sup>RD</sup> STONE DESIGN, INC.  
FOUNDER, ROBERT MIROS  
CALIFORNIA, USA

### THE PROBLEM/SOLUTION SPACE

Inaccurate dosing of liquid medication is a common occurrence with potentially severe consequences. For example, when administering antiretroviral medications (ARVs) to individuals with HIV/AIDS, inaccurate dosing can create viral drug resistance, rendering the drugs ineffective and allowing the virus to spread. Infants and children, with their immature organ and immune systems and small size, are particularly vulnerable to dosing mistakes. Medication errors are nearly three times more likely to result in harm or death for pediatric patients than for adults.<sup>1,2</sup>

Dosages for adult medicines tend to be standardized, making pills a viable option where resources permit. However, because pediatric dosages are generally calculated based on

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patient weight, many medications for children rely on liquid formulations. Misdosing is prevalent; studies show that 40-60 percent of parents and caregivers make errors when measuring liquid medication for their children.<sup>3,4</sup>

The variety of delivery mechanisms for liquid medications increases the potential for error. Dosing spoons/cups, droppers, and oral syringes can be difficult to read, and vary in their increments, units of measure, and volume. Moreover, clinician instructions may not correspond with the units of measure on the dosing instrument. Because of this complexity, caregivers with low reading and numeracy skills are most likely to make mistakes in measuring the correct amount of medication.<sup>5,6</sup>

### ABOUT THE DOSERIGHT SYRINGE CLIP

At Rice University, the Rice 360° Institute for Global Health Technologies seeks to design and implement technologies that improve health and reduce poverty. Beyond Traditional Borders (BTB), Rice 360°'s undergraduate program, challenges students to solve global health problems through real world engineering design. BTB students work in teams to design low-cost technologies that address pressing healthcare needs in resource-limited settings.<sup>7, 8</sup> As of 2012, 45,000 people in 21 countries had benefited from 28 new global health technologies and programs designed by students in Rice 360°'s BTB initiative.<sup>9</sup>



Photo courtesy of 3<sup>rd</sup> Stone Design

*A nurse fills a syringe fitted with the DoseRight clip*

One promising technology that emerged from the BTB program was the DoseRight Syringe Clip. Developed to address the need for accurate pediatric dosing of liquid ARV medications in countries with widespread HIV/AIDs, DoseRight was a simple plastic clip inserted into the top part of the shaft of a standard oral syringe. By limiting the upwards movement of the plunger, the clip preset the amount of medication that could be drawn into the syringe. Produced in multiple lengths and color-coded to correspond with the different dosing volumes, the DoseRight clips could be quickly

and easily affixed to the syringe. Once in place, the clip facilitated the measurement of a more accurate dose regardless of caregiver literacy or visual acuity. Because the clips did not touch the medication, they could be re-used for the same dosage amount given to the same patient. By improving adherence to ARV regimens in developing countries, DoseRight could potentially save many lives.

### ONE CHALLENGE: MOVING OUT OF THE LAB

By pairing students with faculty, clinicians, and mentors in the developing world, BTB teams had designed an impressive portfolio of effective low-cost medical technologies. However, given the temporary nature of the student teams, as well as the intensive focus and specialized expertise needed to take an invention out of the lab and into the market, the program had realized less consistent results in commercializing these solutions. BTB needed a mechanism to help get more of its emerging technologies into the hands of their intended users.

With the DoseRight technology, students and faculty continued iterating the design and field-testing the clips beyond the boundaries of the original course assignment. Using prototypes fabricated in-house, they conducted studies to prove that dosing accuracy increased when the clips were deployed. Significantly, they also lined up DoseRight's first customer. The Clinton Health Access Initiative (CHAI), a leader in global efforts to treat children with HIV/AIDs,<sup>10</sup> was eager to become a partner/customer of the technology. The challenge was finding a development pathway to efficiently transition DoseRight from an interesting concept to a viable product.

### THE SOLUTION: LICENSING TECHNOLOGY TO A COMMERCIALIZATION PARTNER

In an effort to extend the resources, competencies, and support that BTB could apply to its projects, the program leaders began seeking an experienced partner to drive the commercialization of some of its solutions, including the DoseRight syringe clips. As part of this search, they contacted Robert Miros, founder and CEO of 3<sup>rd</sup> Stone Design Inc. Based in San Rafael, California, 3<sup>rd</sup> Stone Design was a privately-held, for-profit product design, strategy, and development consultancy. The company had developed a niche in what Miros called the “go-to-market space.” “We step in when someone has come up

with a good prototype, but they don't really know how they're going to manufacture it at a reasonable cost and get it distributed,” he explained.<sup>11</sup> 3<sup>rd</sup> Stone Design worked with mainstream commercial companies across a diversity of industries. However, the team also had a strong interest in healthcare technologies targeted at developing countries. Accordingly, they used revenue from the company's for-profit projects to subsidize university and nonprofit initiatives in this space. “We still endeavor to cover our costs on these projects, but we have the attitude that there are other advantages—like all the patients who will benefit from the results. Personally, we want to do this work,” Miros said.

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*For something to be successful, it helps if it's simple. The more complex it gets, the more stumbling blocks there are, the more limitations, the more regulatory hurdles you need to go through.*

3<sup>rd</sup> Stone had previously collaborated with the BTB program on another project—a low-cost fluorescence microscope designed for clinics in developing countries with limited access to lab equipment or the required infrastructure (e.g., electricity) to use it. BTB contracted with Miros' team to oversee the production of the first 20 units of the device, which were deployed in field tests focused on the detection of tuberculosis.<sup>12</sup>

DoseRight offered the same basic development challenge; take the concept, manufacture it at a reasonable cost, and bring it to the market. “They [Rice 360°] had seen some initial good results. But parts of the student team were going on to other things. Because it was developed there, the university had certain rights to the technology and wanted to see it move forward,” recalled Miros.

In the case of DoseRight, 3<sup>rd</sup> Stone Design was potentially interested in licensing the technology. However, the team was selective about which technologies made good licensing candidates given the amount of time, resources and capital 3<sup>rd</sup> Stone would have to invest to take the invention from a prototype to a market-ready product. Specifically, the company examined several criteria before making a licensing decision.

### Safety and Effectiveness

At the most basic level, the technology had to be safe and effective. As an adjunct to an oral syringe, there was no safety concern with the dosing clips. Moreover, Rice had done extensive research to verify DoseRight's clinical benefit. "[If] you give a person an oral syringe with a dose clip, they're a lot more accurate than [if you] just give them an oral syringe," Miros stated. "It's statistically proven."

### Sales Volume

Another important metric that 3<sup>rd</sup> Stone considered was potential sales volume, in order to determine whether the product could become self-sustaining. While DoseRight was clearly a low-margin device, sales in developing countries were likely to be driven by nongovernmental organization (NGO) customers like CHAI. Typically, these entities placed relatively high-volume orders to support pilot projects and large-scale rollouts in their target geographies. "If a number of these orders come in, we should be able to make it worthwhile," Miros noted.

In addition to sales in the developing countries, DoseRight also had the potential to generate sales in the developed world. In Western countries, DoseRight addressed an unmet need for more accurate dosing of children's over-the-counter (OTC) medications. "The issue of dosing accuracy, especially as it relates to pediatrics, is a prevalent one that is being discussed at the highest levels of the FDA," Miros explained. "Think about oral Tylenol for infants and kids. Parents are pretty nervous about giving the right amount, especially when it is the middle of their night, and their child has a fever. A clip in the syringe seems like a pretty simple solution." This dual market potential meant a much bigger market opportunity for DoseRight. 3<sup>rd</sup> Stone could also use a differential pricing strategy, charging higher prices in the West to make the clips more affordable in low-resource settings.

### Simplicity

Although he personally enjoyed the challenge of working on technically complex solutions, Miros believed that simpler solutions often represented better market opportunities. "For something to be successful, it helps if it's simple. The more complex it gets, the more stumbling blocks there are, the more limitations, the more regulatory hurdles you need to go through," he said. Miros liked the fact that with the DoseRight clips, "It doesn't take you 25 minutes to understand what the heck it does." The elegant, one-piece plastic design of the clips also meant they would be relatively simple to manufacture. In addition, DoseRight's regulatory path seemed straightforward since it attached to an oral syringe and did not change the fundamental function of that well-proven device. The simplicity of the device convinced Miros that 3<sup>rd</sup> Stone would be able to commercialize DoseRight without external funding from sources such as venture capital (VC). Because VC investors require swift timelines and substantial returns, Miros considered them a mismatch when it came to funding global health products. "The VC funding window of expectation is usually too short or too grandiose for global health application," he explained.

The simplicity of the device was also appealing on another, more practical level; in limited resource settings, expensive medical equipment is often simply abandoned when

it stops working. “We love manufacturing complexity and figuring out novel, clever ways to do stuff, but in low-resource settings, when really complicated equipment breaks, there’s no way to fix it,” Miros said.

### Intellectual Property

Finally, 3<sup>rd</sup> Stone sought technologies with an unencumbered intellectual property (IP) landscape, which ensured freedom to operate and a reasonable chance of securing patents to block competition. “We want to be sure that at the end of it, there is some sort of lockup, or preferential access to whatever it is we’ve helped develop,” Miros affirmed. With DoseRight, the IP landscape looked relatively clear.



The DoseRight syringe clip

With these criteria met, 3<sup>rd</sup> Stone obtained an exclusive worldwide license to the DoseRight technology from Rice University’s BTB program in 2011. The license included certain

requirements, including preferential pricing for countries that are part of GAVI, the Global Alliance for Vaccine and Immunization (a public/private health partnership that works to increase access to immunization in the world’s poorest countries).<sup>13</sup>

Going forward, 3<sup>rd</sup> Stone’s sales and distribution strategy involved working with supporting organizations including NGOs and/or ministries of health to provide bulk sales to developing countries where there was an appropriate need. In the developed world, 3<sup>rd</sup> Stone planned to obtain the required regulatory approvals and pursue an OTC strategy, either through national chains that already sell oral syringes for dosing pediatric medicines, or through large healthcare providers with technology acquisition programs.

With the help of CHAI, the first large-scale delivery of the DoseRight clips was made to a nationwide program focused on Prevention of Mother to Child Transmission of HIV in Swaziland, Africa in 2011. ♦

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### NOTES

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