

**DIABETES
DEVICES**

Will Simpler Devices Tap the Largest Diabetes Market?

For those with type 2 disease, less expensive, “dumbed-down” insulin pumps may be the solution to achieving good glucose control.

BY MARIE SCHILLER, ANDREW FUNDERBURK, SHEELA HEGDE, AND KATHRYN STRAYER-BENTON

- The majority of patients with diabetes fall into the type 2 category. The type 2 population on insulin is not well served by existing technologies.
- The two biggest hurdles to good glucose control in type 2s are a lack of compliance with complicated self-testing and drug regimens, and physician resistance to the adoption of products that require more training time.
- In automating insulin delivery, pumps theoretically match natural insulin secretion better than episodic injections and also solve compliance problems. But they have only penetrated 40% of the type 1 market, and in their current forms, they aren't even an option for type 2s.
- The major diabetes manufacturers and start-ups are now working on simpler, sleeker, lower-cost insulin pumps to address the unmet need in diabetes.
- Health Advances believes these next-generation pumps represent a disruptive innovation that could become an essential part of improving care for the growing population of poorly controlled type 2 patients—without increasing the burden on patients, physicians, or payors.

For many insulin-requiring patients with type 2 diabetes, disease management is complicated, requiring frequent glucose tests and multiple drug regimens every day. One of the most important ingredients in the successful management of diabetes is patient behavior. The more patients adhere to their drug and testing regimens, the better the outcomes. But many aren't compliant, testing less than they should and skipping injections because of the complexity and inconvenience of recommended treatments. It's a problem that would seem to be amenable to technological solutions, and, indeed, over the years many innovative companies have proffered new formulations of insulin, better blood glucose meters, user-friendly insulin injection pens, and ever-smaller insulin pumps, all hoping to make it easier for patients to manage their diabetes.

Incremental innovations, however, have rarely shifted the paradigm in diabetes management, and many technologies that initially looked promising failed, despite the fact that the current requirements of multiple daily insulin injections clearly leave room for improvement. Throughout the history of diabetes care, it has simply been tougher than anticipated for companies to demonstrate that their new technologies can outperform the standard of care—from either a clinical or a market standpoint.

Inhaled insulin is a case in point. Several pharmaceutical companies sought to develop nasally delivered insulin as an alternative to painful injections. Surveys indicated that patients would prefer it, and that those with type 2 diabetes might even begin insulin regimens earlier in the course of their disease with such an alternative to injections. But **Pfizer Inc.** abandoned its inhaled insulin, *Exubera*, when it failed in the marketplace, and both **Novo Nordisk AS** and **Eli Lilly & Co.** also subsequently scrapped late-stage inhaled-insulin programs. (See “*Inhaled Insulin Is Dead. Long Live Inhaled Insulin*,” IN VIVO, March 2008.) The problem: the inhaled insulins of these companies failed to beat the standard of care on the most fundamental criteria: clinical benefit, cost, and ease of use. Although the inhalation devices avoided injections, they were still cumbersome, more expensive than existing delivery methods, and at the end of the day, they delivered the same drug that was available in other well-accepted and less expensive delivery forms.

Nonetheless, there remains a great push to better manage patients with type 2 diabetes, which account for 90 to 95% of all cases of diabetes. Diabetes is already responsible for \$116 billion in direct health care costs, and because type 2 diabetes is largely a condition of aging and obesity, the burden is growing, causing the clinical community, payors, and companies to rethink management strategies for this patient population.

COMPLIANCE: THE BIGGEST HURDLE

In October 2008, the American Diabetes Association and the European Association for the Study of Diabetes updated treatment recommendations for type 2 diabetes. Despite the availability of additional drugs over the past few years, they again kept basal insulin as a second-line option after lifestyle changes and the drug metformin, and intensive insulin therapy as a third-line option. These recommendations underscore the importance of insulin as a therapy in the type 2 patient.

But recommendations do not address lack of compliance with prescribed drug therapies. In part, inadequate compliance stems from the fact that many type 2 patients don't perceive the great need to comply with recommended therapies because they view their disease as less life-threatening than type 1 diabetes, and, indeed, the majority of type 2s don't bear the same risk of hypoglycemia, ketoacidosis, and death that type 1s face. Importantly, patients with type 2 diabetes develop increased insulin resistance and decreased beta cell function as their disease progresses, to the point where some require as many as four shots of insulin a day. This means they are being asked to adopt new habits late in life, which is one factor contributing to less than optimal compliance with testing and therapy prescriptions.

It is simply difficult for many patients to fit four daily injections of insulin into their lives. They need to carry around a multitude of supplies, and frequently complain that it is especially difficult to comply at lunchtime, when their disease becomes very visible to the public. Patients want to feel normal and don't want to have to excuse themselves to inject. Or, many have jobs where lack of privacy or time constraints interfere with mid-day injections. So although hitting HbA1c targets is a priority among all patients, many are falling short. Based on prescription refill rates, compliance for type 2 patients on insulin could be as low as 50%.

**TODAY'S INSULIN PUMPS:
A PARTIAL SOLUTION**

The insulin pump is one technology that has enhanced the process of diabetes management: it offers patients the ability to control their diabetes more precisely with fewer injections. These wearable devices automate insulin delivery throughout the day, according to a patient-specific program, and would thus seem to be the solution to the need for the day-long administration of basal and bolus insulin. Nevertheless, while insulin pumps on the market today have penetrated 40% of the type 1 diabetes population (for which insulin pumps are reimbursed), they have only penetrated 1% of the insulin-requiring type 2 population (which usually doesn't receive reimbursement).

Today's pumps are complicated devices, requiring patients to customize delivery of their insulin by inputting several basal in-

Exhibit 1

Selected Companies Developing New Insulin Pump Technologies
TRADITIONAL AND SIMPLIFIED PUMPS

Product Category		
Simple, Lower Cost	Undetermined	Full-Feature
<ul style="list-style-type: none"> ▪ CeQur Ltd ▪ Medipacs ▪ Seattle Medical Technologies ▪ Starbridge Systems ▪ Valeritas 	<ul style="list-style-type: none"> ▪ NanoVic ▪ NiliMedix ▪ Sensile Medical ▪ Medtronic 	<ul style="list-style-type: none"> ▪ Abbott ▪ Debiotech ▪ M2 Medical ▪ Medingo ▪ Novo Nordisk ▪ SpectRx ▪ Therafuse

SOURCE: Health Advances

ulin rates, bolus options, correction factors, and carbohydrate ratios. Patients who are good candidates for pumps have to go through several training sessions before they're even allowed to take them home. That complexity has presented an adoption hurdle for type 1 patients and their physicians, and it is one of the main reasons physicians don't seriously consider them for their type 2 patients.

Health Advances LLC believes that existing devices are still too complex: what physicians want is a simpler system that type 2 patients will embrace because it allows them to finally achieve better glucose control while still maintaining normalcy in their lives. Cost is also a key factor in this equation.

Based on its extensive research with physicians, patients, payors, and companies, Health Advances believes that the next disruptive technology in diabetes management will come in the form of lower-cost, easy-to-use insulin pumps for the masses. There are at least 16 simplified pumps in development, by companies like **CeQur Ltd.**, **Seattle Medical Technologies**, **Valeritas Inc.** (owned by **BioValve Technologies Inc.**), and **M2 Medical Inc.**, among others. (See Exhibit 1.) Valeritas, for example, recently raised \$30 million from top tier venture firms.

Even more telling, **Medtronic Inc.**, the leader in the traditional insulin pump market, announced that it is increasing its R&D spending on diabetes by 35% in 2008 to accelerate the development of next-generation diabetes devices that are simpler to use. Over the next five years, simple, lower-cost insulin pumps will create new opportunities for traditional pump companies to access previously untapped patient groups, and for other companies—drug companies and companies with continuous glucose monitors, for example—to establish new sources of competitive advantage.

DIMINISHING RETURNS IN THE INSULIN PUMP MARKET

The evolution of insulin pump technology offers a classic example of perpetual innovation and diminishing returns. Since 1983, when the MiniMed 502 series was introduced to the market by Alfred Mann's company—Pacesetter Systems (now **Medtronic MiniMed Inc.**)—incremental improvements have resulted in smaller devices with increasingly complex features. The great complexity of insulin pumps has rendered them extraneous for the vastly larger population of four million type 2 diabetes patients who require insulin, but who do not necessarily need or are reluctant to use the more intricate

devices. They are primarily appropriate for a narrow market consisting of a subset of the one million type 1 diabetes patients in the US.

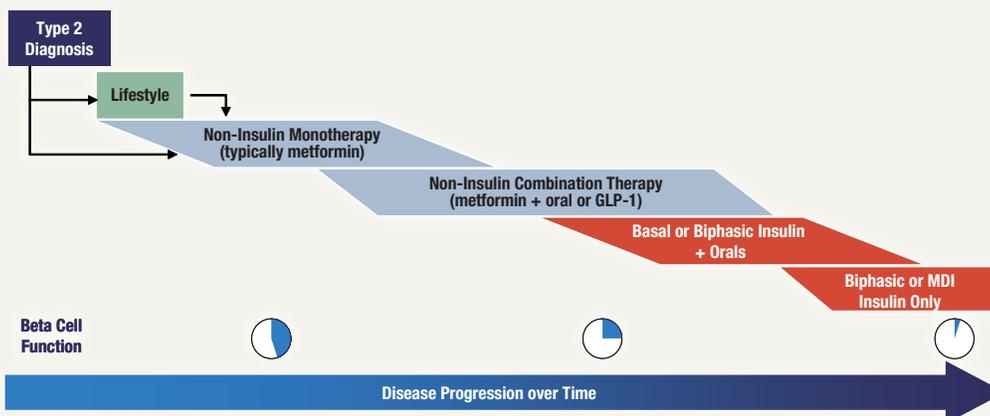
The device industry has not yet produced pump innovation that drastically shifts and expands the market for new diabetes treatments. But such disruptive technology may be on the horizon, as a large number of companies develop simple, lower-cost insulin delivery systems—sometimes labeled “dumb” or “patch” pumps—that may provide compelling benefits for a broad population of diabetes patients and their health care providers. These new pumps are de-featured versions of insulin pumps, often smaller, and frequently constructed without tubing (patch pumps). The patient never sees the needle and the insertion process is automated. In some designs there is no separate programmer and patients can bolus directly from the pump.

These elegantly simple devices may benefit two- to three-fold the number of patients in the US currently using complex pumps, and they may also open up the European and Asian markets by leapfrogging traditional insulin pumps.

Capturing this market will not come without challenges. Companies will have to employ low-cost technology without sacrificing the quality of the design. Indeed, because diabetes is a price-sensitive market, many companies hope to keep average selling prices competitive with insulin pens, which are currently enjoying a ramp-up in adoption. They will have to be easy for physicians to teach and patients to use. And insurance providers will have to agree to pay for them. Continuous glucose monitors (CGMs) on the market today are a testament to the importance of reimbursement. Lack of reimbursement for CGMs has stymied adoption, despite the fact that studies have validated their usefulness in helping patients avoid glycemic variability. (A few payors are now finally making the decision to cover CGM after the recent publication of results from a major trial conducted by the Juvenile Diabetes Research Foundation).

Exhibit 2

Traditional Type 2 Diabetes Treatment Paradigm



SOURCE: Health Advances

DIVERSE PATIENTS WITH DIVERSE NEEDS

The different physiological needs for insulin between type 1 diabetics (inability to secrete either basal insulin to regulate glucose in the liver or insulin to regulate diet-introduced glucose) and type 2s (progressive decline in insulin secretion as beta cell function deteriorates) results in differences in insulin coverage requirements, dosing sensitivity, and dosing amounts. Type 1 patients require more complex management because they are

more sensitive to insulin than type 2 patients, and doses have to be regulated very carefully as needs change based on diet and exercise. Type 2 patients usually require more insulin and have fewer issues with hypoglycemia because of their insulin resistance.

There are also emotional and psychological differences, which have a very real impact on patient adherence and insulin delivery choices. Type 1 diabetes patients view insulin as a lifeline. They are willing to do more to regulate blood sugar and insulin levels, and they are generally seen as a more compliant patient group. Most type 1 patients desire and use the added functionality afforded by ever-improving pens and insulin pumps.

For type 2 patients, the disease often presents a greater emotional hurdle, in part because it requires them to adopt new habits, and in part because they have a different perception of their need for insulin, especially when they first begin therapy. These patients often resist moving to more aggressive insulin management, which ultimately requires them to administer multiple daily injections. A pump overflowing with tubes and buttons can therefore be overwhelming.

Coverage for type 2 patients is also more complicated because payors don't perceive as much of a need for advanced insulin delivery options as for type 1s. In fact, even if a physician or patient desires to initiate pump therapy, unfavorable reimbursement policies can often prevent initiation.

INNOVATIONS IN INSULIN DELIVERY

Companies have responded to the multifaceted needs of diabetes patients on insulin treatment with three major types of insulin delivery devices: syringes; pens, which simplify the education and injection process; and pumps. (See Exhibit 3).

With pens, patients do not need to draw the insulin into a syringe: they can just dial in the dose they need. Pens remove several steps from the vial-and-syringe injection process and capture significant time savings, especially for patients who require multiple daily injections and flexible lifestyles. Despite their advantages in ease of use, however, only 20 to 30% of insulin users in the US use pens because of a lack of reimbursement that hindered adoption earlier in the evolution of the products.

Early in their development, insulin pens cost more than vials and syringes and were listed under tier 3 reimbursement, at which

Exhibit 3
Insulin Delivery Devices (US)

	Vials and Syringes	Pens	Pumps
Insulin Delivery Options			
		<i>Reusable and Disposable Options Available</i>	<i>Traditionally with Tubing; Body-Worn Now Available</i>
Brands	<ul style="list-style-type: none"> Syringes: Becton Dickinson, Private Label Insulin: Eli Lilly, Novo Nordisk, Sanofi Aventis 	<ul style="list-style-type: none"> Eli Lilly Novo Nordisk Sanofi Aventis 	<ul style="list-style-type: none"> Medtronic Smiths-Deltec J&J/Animas Roche Insulet
Advantages	<ul style="list-style-type: none"> Inexpensive (many needles have no copay) 	<ul style="list-style-type: none"> Easy to use and train Shorter needle 	<ul style="list-style-type: none"> Matches "healthy" pancreas delivery Injection once every 2-3 days
Limitations	<ul style="list-style-type: none"> Must carry multiple syringes, vials and ancillary supplies Must dispose of sharps Longer needles Syringe stigma Does not reduce injection frequency 	<ul style="list-style-type: none"> Must carry pen and disposable needle supply Disposable pens priced at premium to vials Must handle needles and dispose of sharps Does not reduce injection frequency 	<ul style="list-style-type: none"> Connected to patient via tubing Unnecessary complexity for type 2 patients Often prohibitively expensive; not reimbursed for many type 2 patients Difficult to train/teach

SOURCE: Health Advances

patients had to bear a higher co-pay. Type 1 diabetes patients were often willing to pay the higher cost for the increased convenience. On the other hand, type 2 diabetics who do not take insulin as frequently and who are not as insulin sensitive were slow to adopt insulin pens. The pen market expanded when pens moved from tier 3 into tier 2 positions on payors' drug formularies.

Pens also have disadvantages: they still require patients to handle a needle, and they don't address the issue of injection frequency. Even with a therapy that's as easy to administer as a pill, the more times a day that a patient is required to take a medication, the more compliance falls off. Nor do pens help patients completely match normal insulin secretion patterns. That's the promise of insulin pumps, which offer continuous insulin coverage tailored for a particular patient. Insulin pumps have in fact been around even longer than pens. Despite their immense promise, however, they have experienced much slower adoption by patients and providers than initially expected.

TRADITIONAL PUMPS SERVE ONLY A SELECT POPULATION

The first insulin pump, developed by Dr. Arnold Kadish in the 1960s, was a clunky, backpack unit. The *AutoSyringe* model—known by many as the “Big Blue Brick,” developed by serial entrepreneur Dean Kamen in the late 1970s—was the first commercial

pump. This pump was still clunky and not user friendly. During the 1980s, pumps were only used as a last resort for patients suffering significant complications and waiting for pancreas transplants.

Miniaturization was the first step forward for these bulky pumps. As pumps shrank in size, their use spread to a wider population of mostly type 1 patients. The second order of innovation for insulin pumps was increased functionality: multiple basal rate and bolus dosing options, carbohydrate calculators, and simple algorithms to account for previously dosed insulin. Some pumps even started including discrete blood glucose testing as part of the unit. Currently, the technology is edging ever closer toward the vision of a constantly self-regulating device.

However, these innovations serve to make insulin pumps more effective only for insulin-sensitive type 1 patients who have good insurance coverage and who are motivated to learn how to navigate the complex menus and controls of the pumps. Currently about 40% of type 1 patients on insulin treatment in the US use a pump. Less than 1% of the much larger group of type 2 patients on insulin treatments use an insulin pump. (See Exhibit 4.) Outside the US, pump therapy is even more limited. For example, in Europe, only 10 to 15% of type 1 patients and virtually no type 2 patients use insulin pumps today.

CeQur Ltd: Conforming to the Lifestyle of the Type 2

Joe the dishwasher comes from a long line of type 2 diabetics. He has the disease, and so do his sister, brother, mother, and father. Despite his physician's recommendation that he take four shots of insulin a day, he takes, at best, two, and some days he takes even fewer. Joe has neither the time, nor the privacy at work to inject himself during the day, and he doesn't have the space to store a kit containing long-acting and short-acting insulin supplies and glucose testing paraphernalia. That's the real world experience of a large number of patients with type 2 diabetes. Insulin delivery devices don't fit into their lives, and because their glucose levels aren't well managed, they don't feel as well as they could today and face the complications of poorly controlled diabetes down the road.

James Peterson, chairman and CEO of new company CeQur Ltd., would like physicians and diabetes educators to be able to offer patients these choices in the near future: “You can use syringes in vials, or

pens. Here is one pen for your long-acting **Lantus**, and another pen that contains your rapid-acting **Humalog**. You open the needle package and put on a fresh needle, dial in the number of units to be administered, clean the injection site, and then push the injector and hold it against your skin for five seconds so insulin doesn't leak out. Then, look for somewhere to dispose of the needle. And here is a kit to carry around all your insulin supplies during the day. Or, instead, you can stick a patch insulin pump on your body, press a button to dispense bolus insulin when you eat, and replace the patch after three days with a new one.” That's the convenience that CeQur, the developer of a new insulin patch pump, aims to offer patients with type 2 diabetes, according to Peterson.

Peterson is familiar with the burden of living with diabetes; his daughter has type 1 diabetes, and he has been on the board of trustees of the Joslin Diabetes Center for years. In 2003, he retired as CEO of Haemonetics Corp., and after a stint with War-

burg Pincus where he advised on diabetes deals, he continued to be driven by his bio-engineering sensibilities. Casting about for a project in diabetes, he became an early investor and chairman of M2 Medical Inc., a start-up developing a disposable insulin delivery system, initially for patients with type 1 diabetes. (De Novo Ventures and Novo Ventures, the venture capital arm of Novo Nordisk AS, are also investors in M2 Medical.) After moving the company from Copenhagen to Sunnyvale, California, and getting the company financed, Peterson returned to Switzerland, where he lives.

Back in Europe, Peterson was approached by some executives from the Danfoss Group, a multibillion dollar industrial firm focusing on heat transfer and fluid movement technologies. Danfoss had been looking to convert some of its in-house technologies to medical products, and it had invented a microfluidic technology for infusing insulin. The product was fully invented, the company had completed the electronic design and built

No incremental innovation in the tradition insulin pump market over the next three to five years is likely to increase use significantly to include all type 1 patients or drive expansion into the type 2 market: not all type 1 patients have the support networks necessary to manage pumps or the insurance coverage to access them; and although new insulins or fully automated systems (including continuous glucose monitoring) may move more type 1 patients to pump therapy, it is more likely that these innovations will merely serve the existing pump market, particularly in light of a persistent lack of reimbursement for continuous glucose monitoring.

A LARGER MARKET AWAITS

Tapping the much larger, unrealized market of insulin-requiring patients not currently on any pump therapy will require a different technology. Enter the dumb pump, a simple, lower-cost, continuous insulin delivery system. The concept is a small, wearable, low-profile device that delivers basal insulin continuously and bolus insulin with the push of a button. These devices have the potential to much more closely match the needs of type 2 patients, who are asked to give themselves predetermined amounts of insulin throughout the day. Dumb pumps will help patients better adhere to their therapy. But to

gain broad acceptance, they must compete favorably with the standard of care on clinical benefit, cost, and ease of use, and these requirements are defined by the daily burden of managing and living with diabetes.

Most type 2 patients are “managed” by general practitioners who have about 15 minutes for each patient visit. Teaching a type 2 patient about multiple basal rate alternatives and complex carbohydrate calculators is not an option: Interviews with patients using pens, a technology that is far less complicated than existing pumps, reveal that some still read the instruction manuals frequently.

Companies developing simplified insulin pumps will need to drive home the easy-to-use, easy-to-train message, while proving quality and reliability. They’ll need to design a small footprint, establish clinical benefit, and achieve favorable reimbursement to compete successfully against the gold standard, first-line insulin treatment: the easy, one-shot injection, whether via syringe or pen. While burdensome, the traditional multiple-daily injection regimen is at least familiar and cost-effective.

The new pump companies will need to conduct clinical trials to prove to payors that devices are safe and effective. Companies should also look for areas of potential clinical

the first prototype molds, and it had done glucose clamp studies in patients.

Peterson recommended that Danfoss spin out the technology—a patch insulin pump—to a separate company, which Danfoss did, forming CeQur in January 2008. Danfoss invested, retaining 40% of the company, alongside venture capital firms Endeavour Vision, Orion Bioventures, VI Partners, and angel investors.

Peterson says that when he dug into the type 2 diabetes world, he was astonished by the magnitude of the patient need—and the enormity of the opportunity for type 2 pumps could reach \$2-4 billion a year in the US and Europe alone.

CeQur has designed a disposable pump that is easy for physicians to teach and for patients to use. A patient attaches the patch pump to the body in an inconspicuous place (it has an adhesive backing), and pushes a button to automatically insert a plastic catheter. The pump will continuously deliver basal insulin at a stable rate for three days, and at meal times, the pa-

tient pushes a button to administer bolus insulin. Different dosages of basal insulin are offered in devices distinguished by different colors, so a physician might tell a patient, “I want you to take the basal insulin that comes in the green patch pump.” After three days, the device vibrates and beeps to alert the patient that its time to discard it and replace it with a new one. CeQur thus keeps pump design and training very simple. Peterson believes that the simple design will help the company keep its cost of goods down so that it can effectively compete with pens and other technologies.

CeQur anticipates beginning user trials on its patch pump, which is eligible for the 510(k) approval track, in the US next year, and it expects to launch in Europe at the same time. The company is an early mover in the patch pump market, and Peterson admits that CeQur faces the challenge of educating physicians about a new option for a new group of patients. “Do the physicians that are pump-driven

prescribers for type 1 patients understand how to take care of type 2 patients? There is a schism out there,” he says. Type 1 patients need more sophisticated management strategies and technologies because it’s important to fine tune their insulin, but type 2s simply need consistent and regular dosing, he explains.

There is a large number of potential partners with access to the appropriate distribution channels, Peterson believes—companies such as Eli Lilly & Co. and Novo Nordisk AS on the insulin side, and glucose-testing companies like Johnson & Johnson, **Roche**, **Bayer AG**, and **Abbott Laboratories Inc.** In the future, he sees the linkage of CeQur’s patch pump, which incorporates electronics, with the blood glucose meters of these companies, so that physicians can ultimately download both the blood glucose readings and the amount of insulin that’s been dispensed. The latter information is today absent or unreliable because it is self-reported by patients.

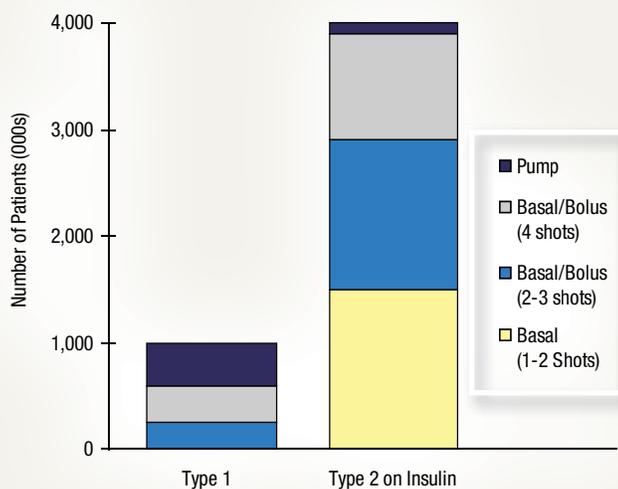
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advantage. One area may be reducing glycemic variability, an end point that is gaining attention in the clinical community as one of the causes of diabetic complications.

At the same time, the dumb pumps will have to offer a much different ease-of-use and value proposition than traditional pump therapy, which requires trained nurses and lengthy titration periods with frequent check-ins. These demands prevent the majority of physicians from prescribing traditional pumps for type 2 patients. To gain the endorsement of care providers,

Exhibit 4

Insulin Use in the United States 2007



SOURCE: Health Advances

training for the new, simplified pumps must be considered as easy as training for insulin pens. Only if manufacturers can meet these criteria, will physicians and nurse educators embrace the opportunity to afford diabetes patients the benefits of continuous infusion at a reasonable price point, without the burden and confusion of extra features. The low-cost pumps must also prove that although simpler, they are still as robust and reliable as conventional insulin pumps.

Companies mindful that these products will be attached to patients around the clock, and that patients want them to remain inconspicuous, will also have an advantage. Dumb pump designs eliminate tubing, and they should also keep a flat profile and attempt to be flexible to stay true to the vision of a patch. At least one early-stage company has chosen a smaller, sleeker design with the trade-off of more frequent replacements. (The replacement cycle of devices and the limitations on miniaturization are tied to how much insulin the devices can contain. In the future, extremely concentrated forms of insulin may help companies reduce the size of devices even further.)

Finally, keeping costs low is critical to attaining favorable coverage. The market will likely bear a slight premium over

existing pen rates, and will expect a significant discount to traditional pumps (which are listed at \$6,000 up front, with disposables listed at \$2,500 per year.)

KEEPING IT SIMPLE

Insulet Corp. is a forerunner in the field of next generation pumps, and it is both an example of the great promise and significant challenges in the market place. Insulet commercialized the first disposable insulin pump that is attached to the body without tubes with an automated insertion process. Its *OmniPod* is a small, disposable insulin pump with the full functionality of traditional insulin pumps for the type 1 diabetes population. Patients love it; the company reported year-on-year revenue growth of 167% at the end of third quarter 2008. However, because Insulet is offering a very complex device to a demanding population, the company faces the potential risk of the failure of numerous components and a cost of goods that is still so high that the company has yet to turn a profit. Insulet estimates that it will report a loss of \$75 million in 2008 (although it is beginning to improve its margins). By keeping it simple, the new patch pump companies hope to keep costs down.

While being cost effective, simplified pumps also will have competitive advantages because they'll be easier to use and more convenient than any other insulin delivery methods. A body-worn pump is more convenient than carrying a load of syringes or pens, and it will become especially attractive as design innovations eliminate the need for tubing and extraneous devices. These new devices may take the form of small patches worn close to the skin, without separate electronic components. As simplified pumps follow the industry trend from reusable systems toward disposable models, design and use will be simplified even further. Some companies are developing disposable systems designed to last for several days instead of years, and thus patients will avoid maintenance problems and costs, as well as expensive up-front purchases. Limited software and limited dosing flexibility are two examples of how the complexity—and therefore the cost—of devices is being reduced. *CeQur Ltd.*, for example, has found a way to balance the need for pump simplicity with the need for patient-specific dosing. (See sidebar, "*CeQur Ltd.: Conforming to the Lifestyle of the Type 2*".)

SERVING NEW PATIENTS AND DISRUPTING THE STATUS QUO

The introduction of simplified insulin pumps will shift insulin delivery technology out of its traditional pattern of incremental change and diminishing returns. Initially, Health Advances believes that simplified pumps will not directly challenge the full-feature pump market; rather, these systems will create a differentiated market among type 2 patients who don't currently use pumps because they're either injecting insulin multiple times daily or still injecting once daily. These patients will benefit from more intensified insulin regimens.

Over time, however, along the lines of other disruptive technologies, dumb pumps may improve to the point that they migrate back to a portion of the type 1 market. This may be particularly relevant for the 50 to 60% of type 1 diabetics in the US on insulin treatment who do not currently use full-

feature pump technology, and these pumps may even make incursions upon the patient segment currently on traditional insulin pumps. The recent introduction of continuous glucose monitoring and the timing of a closed-loop system (the so-called artificial pancreas) will be crucial to sustaining the current type 1 pump market. If a closed-loop system is delayed, some current type 1 patients may opt for the simpler systems.

These low-cost pumps also have a potentially enormous opportunity in value-oriented international markets. The cost of traditional insulin pumps and a lack of outcomes data have restricted pump use to date in Europe and Asia. Patients' resistance has also been greater in these countries than in the US. The simplified pumps offered at a lower price point should drive uptake in both type 1 and type 2 patient segments outside the US. Asian markets are increasingly attractive targets as the size and growth of their diabetes population far exceeds that of the US and Europe. China, for example, offers an enormous untapped market for lower-cost, de-featured alternatives to medical devices sold to Western markets. The Middle East, which has one of the highest rates of diabetes in the world, is another potentially large market.

Ultimately, the market for simplified pumps may prove to be two- to threefold greater (in volume) than the current market for traditional pumps. Whereas the traditional insulin pump market has been slow to evolve and is only now reaching the \$1 billion point in the US, many believe the simplified pump market will be larger and evolve much faster.

LANDSCAPE AND BUSINESS MODEL CONSIDERATIONS

There are many companies on the horizon with both traditional and simple pump designs, and more are expected to enter the field over the next few years. Many of the companies with simple designs are venture-backed and are planning to pursue the commercialization path that other pump companies, such as the Animas division of **Johnson & Johnson** and Insulet, have followed.

However, those that want to follow the model of Insulet will face the challenge of needing to raise significant capital

in a skittish market, to build a commercial organization that can compete against Medtronic, which has dominated the traditional pump market for the past 20 years. The question is whether this is the optimal model for these simple pump companies to follow. With the IPO market closed, valuations from multiple venture capital rounds may become too high for potential acquirers to swallow. Perhaps the best approach today would be to keep these companies lean, launch in a few select markets, and then position them for acquisition by several types of potential acquirers: the established insulin pump manufacturers, companies with glucose monitoring franchises, or insulin manufacturers seeking delivery systems to help differentiate their product portfolios. Given the modest product differentiation of insulin competitors, new delivery options are a natural route to competitive advantage.

Simple pumps could create a new opportunity for pump companies to access previously untapped patient groups, and for other companies to establish new sources of competitive advantage, based not on top-of-the-line technology for the few, but on simple, low-cost, accessible technology for the many.

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