



DIABETIC INVESTOR

“Make the Connection” David Kliff, Publisher

ADA 2009

This year’s American Diabetes Association Annual Scientific Sessions can best be summed up by a conversation Diabetic Investor had with a noted researcher when he indicated that although the conference was not as well attended as in past years, it was refreshing to hear everyone talking about diabetes again. This may seem like an odd statement considering this conference is all about diabetes, but it does reflect how, in past years, the conference has strayed somewhat from focusing on how everyone can do more to fight the epidemic growth rate of diabetes and discover more effective treatment options for the millions of patients with diabetes.

As per usual, several major studies were discussed and, in following ADA tradition, researchers debated the relevance of these studies. Once again, these major studies appeared to create more questions than answers. However, what became apparent to Diabetic Investor is the changing nature of how physicians, researchers, drug and device companies view diabetes. While there may be disagreement on which patients should follow an intensive treatment regimen and the benefits of

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This fact extends not only to how patients are treated but how they are monitored. Although the exhibit hall was not as crowded as it has been in the past, there was no shortage of companies touting their latest technological advancements. No longer content to offer single system solutions, device companies are moving toward a world where devices not only communicate with a patient’s computer or cellular phone, but also bring the healthcare professional, educator or health coach into the loop. This trend towards greater connectivity has many implications and not just for the patient.

One area that is not undergoing

any change is the battle between drug and device companies over who has the best drug or device. It seemed as if each day a new press release came out stating that drug A outperformed drug B and then the next day the company for drug B would issue a release stating that drug B outperformed drug A. Diabetic Investor fully understands this back and forth nature of the drug business, but we must admit this tit for tat battle is wearing just a little thin. The best example of just how ridiculous this has become came on Sunday evening when Novo Nordisk (NYSE:NVO) and Amylin Pharmaceuticals (NASDAQ:AMLN) conducted their investor briefings at the same hotel, on the same floor and just hours apart. Officials at both companies insisted this was just a coincidence and

Make the Connection continued page 2

not by design... And Diabetic Investor has a bridge in Brooklyn that you can buy for a dollar.

Before we begin a detailed look at each aspect of the conference, it's worth noting that for the first time in years the rumor mill at the show was relatively tame. Typically at these conferences rumors fly over who's buying who or about some hot new product that's about to take the diabetes world by storm. Perhaps it's the lousy economy and the fact that dollars are tight all over, but Diabetic Investor didn't see a single device that had the wow factor. There was nothing that stood out and made someone think that this device could truly revolutionize diabetes. As indicated before, there was no shortage of technological solutions to diabetes; however, the vast majority of these new technologies were evolutionary, not revolutionary. Perhaps the device companies have finally awakened to the fact that technology by itself is not the solution, but it's the practical use of the technology that makes a real difference. This would be refreshing and a major step forward for the diabetes device industry; however, Diabetic Investor believes this has more to do with the economy than the device companies finding religion.

RECORD, ACCORD, VADT and BARI 2D

The conference got off to a fast start when on Friday afternoon results of the RECORD trial were released. In a desperate attempt to save what's left of their Avandia franchise, GlaxoSmithKline (NYSE:GSK) conducted a study that followed more than 4,000 patients and compared patients taking Avandia in combination with older treatments against patients on more traditional therapy options. According to the results of the trial, Avandia did not increase cardiovascular risk when compared to competing therapy options.

While there were many who debated the merits of the trial and questioned whether or not the trial was well designed, this is all chatter as the results really don't matter all that much. Avandia began its slow death march back in 2007 when Dr. Nissen ambushed the company with his now famous (or infamous, depending on your point of view) meta-analysis. Sales of Avandia, which reached over \$3 billion back in 2006, have fallen to \$1.5 billion in 2008 and continue to fall further in 2009.

Diabetic Investor does understand why GSK conducted the trial; however, we question their quest to resurrect what is clearly a dying drug. RECORD was doomed from the start as researchers began bashing the trial even when they had no results. The fact is that

It's well known that besides cardiovascular concerns, Avandia has been associated with an increased incidence of bone fractures, which goes along with its other known side effects of edema and weight gain. Quite frankly, the more GSK tries to prove Avandia is a good drug, the more ammunition competitors have for bashing it. (You just know the Merck (NYSE:MRK) sales reps love it each time GSK does this.) GSK does have some promising new diabetes therapies in their pipeline and should be concentrating on bringing these new compounds to market rather than trying to save the dying Avandia franchise. The horse has left the starting gate and there's no way the race is starting over.

regardless of the results, they were already tainted from the beginning and GSK had absolutely no chance of winning over the hearts and minds of physicians or patients.

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Speaking of starting over, the results of the ACCORD trial were very intriguing. Designed to examine the effects of intensive glucose control in patients with type 2 diabetes, over 10,000 patients were assigned to receive either intensive therapy (target an HbA1c below 6%) or standard therapy (target HbA1c range between 7 to 7.9%). Published in the *New England Journal of Medicine*, the researchers concluded, "As compared with standard therapy, the use of intensive therapy to target normal glycated hemoglobin levels for 3.5 years increased mortality and did not significantly reduce major cardiovascular events. These findings identify a previously unrecognized harm of intensive glucose lowering in high-risk patients with type 2 diabetes."

The authors go on to state, "However, as compared with the standard-therapy group, the intensive-therapy group had a relative increase in mortality of 22% and an absolute increase of 1.0% during the follow-up period, with similar differences in death from cardiovascular causes. This increase in mortality is equivalent to one extra death for every 95 patients who were treated for 3.5 years."

Perhaps trying to find a silver lining among the dark clouds the authors stated that intensive control may have some benefits noting “These patterns with respect to mortality and primary outcomes suggest that if there is any benefit associated with intensive glucose lowering, it may take several years to emerge, during which time there is an increased risk of death. This intriguing possibility can be answered only by further research.” (This last line is worth noting and one of the main reasons physicians who actually treat patients are so frustrated. Further study is great but they need help now on what to do with their growing type 2 patient population.)

Looked at in its entirety, there were some interesting contradictions within the ACCORD data. For example, patients who quickly lowered their HbA1c levels during the first year of treatment appeared to have a lower risk of death. Mortality risk increased in the intensive group only for patients with HbA1c of greater than 7% compared to the standard therapy group where risk increased with HbA1c levels between 6 and 9%.

In sharp contrast to ACCORD were the results of the VADT trial. According to William Duckworth, MD, director of diabetes research, Carl T. Hayden VA Medical Center, “Initiation of intensive control in the first 15 years after diagnosis of type 2 diabetes reduced the risk of cardiovascular events, including mortality, but initiation 16 to 20 years after diagnosis yielded no such benefit. Further, initiation of intensive control 20 or more years after diagnosis increased the risk of CV events.”

VADT was a 7.5 year trial which studied the effects of intensive glucose control on cardiovascular disease risk in almost 2,000 veterans. Patients were assigned either intensive or standard control. All the patients had poor control hav-

Diabetic Investor also sees both ACCORD and VADT supporting our belief that GLP-1 therapy offers one of the most promising compelling options for treating patients with type 2 diabetes. Besides their proven ability to lower glucose levels, GLP-1 therapy at worst is weight neutral and at best promotes weight loss. Additionally, there is little risk of hypoglycemia let alone severe hypoglycemia. Lastly, evidence is emerging that GLP-1 therapy also helps lower the patient’s blood pressure. Whether this lowering of blood pressure is achieved because the patient loses weight or the results are due to the drug really doesn’t matter. Given the FDA’s new guidelines for approving type 2 drugs, few, if any, compounds offer the list of benefits that GLP-1 therapies have to offer.

ing failed to respond to oral drugs at maximum dosage or insulin. The baseline HbA1c for trial participants was 9.5%.

Some interesting findings from VADT:

HDL levels played a strong role in reducing cardiovascular events and total mortality. For every 10 mg increase in HDL above baseline, patients had an 88% decrease in risk for cardiovascular events and mortality, a 50% decrease in risk for first primary cardiovascular event and 55% decrease in risk for all-cause mortality.

In both the intensive and standard groups, patients who had severe hypoglycemia had an 88% increase in primary cardiovascular events and a threefold increase in death. These findings seem to concur with ACCORD as severe hypoglycemia was associated with higher risk of death in both treatment groups; however, hypoglycemia did not account for overall mortality findings. Denise Bonds, MD, MPH, project officer for ACCORD at the National Heart, Lung and Blood Institute, National Institutes of Health, stated “Hypoglycemia was felt to play no role in most deaths.”

Speaking about VADT, Stephen David, MD, chief of the division of diabetes, endocrinology and metabolism at Vanderbilt University stated “It is important to note that this association between severe hypoglycemia and MI and mortality occurred in both the

intensive and the standard group, in contrast to prior perceptions that such hypoglycemia was just a problem with people on intensive control.”

Diabetic Investor will leave it to the many pundits in the diabetes research world to debate the contrasts between these two trials. Instead, we believe it’s vastly more important to focus on what both ACCORD and VADT tell us. Simply put, when it comes to treating type 2 diabetes, there is no such thing as a one size fits everyone approach. Equally important is the fact that physicians treating type 2 patients must look beyond the patient’s diabetes and consider additional factors when designing a treatment regimen. As noted in the ACCORD trial, “our study has identified a previously unrecognized harm of intensive glucose lowering in high-risk patients with type 2 diabetes mellitus and high glycated hemoglobin levels.”

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patient's blood pressure. Whether this lowering of blood pressure is achieved because the patient loses weight or the results are due to the drug really doesn't matter. Given the FDA's new guidelines for approving type 2 drugs, few, if any, compounds offer the list of benefits that GLP-1 therapies have to offer. (More on GLP-1s later in this issue.)

This is also true when you add in the results of the BARI 2D Study Group. BARI randomly assigned nearly 2,400 patients with both type 2 diabetes and heart disease to undergo either prompt revascularization with intensive medical therapy or intensive medical therapy alone and to undergo either insulin-sensitization or insulin-provision therapy. Also published in the *New England Journal of Medicine*, the group concluded "Overall, there was no significant difference in rates of death and major cardiovascular events between patients undergoing prompt revascularization and those undergoing medical therapy or between strategies of insulin sensitization and insulin provision."

While a great deal was made of the results of BARI, Diabetic Investor sees BARI as just further evidence of the complex nature of treating type 2 patients. What it really says is something we have known for some time - diabetes cannot be looked upon as a stand-alone disease state. The fact is diabetes is part of a dangerous triangle that includes cardiovascular health and obesity. This is why physicians, primary care physicians in particular, carry such a heavy burden when treating their type 2 patients. The truth is, in a perfect world, when designing a treatment regimen for a type 2 patient, multiple disciplines are required. And, as we all know, we do not live in a perfect world.

When it comes to treating type 2 patients, physicians, more than

ever, need clarity and what they are getting is conflicting messages. Depending on your point of view, a strong case can be made for ignoring the guidelines issued by the ADA, which call for getting a patient's HbA1c to 7% or below. Some would even argue that the American Association of Clinical Endocrinologists (AACE) guidelines of 6.5% or below are dangerous. This seems to fly in the face of the results of the landmark DCCT trial.

The way Diabetic Investor sees it, we stand at a critical intersection

The way Diabetic Investor sees it, we stand at a critical intersection when it comes to offering guidelines to the people who actually work with diabetes patients each and every day. Do we continue to offer conflicting research results that make it next to impossible for a physician when designing a treatment regimen? The situation has become so bad that all too often physicians ignore these mixed messages and proceed using nothing more than their gut instincts. To solve this problem, the diabetes community should band together and state clearly that diabetes is not a one size fits all disease state that can be treated using just one approach. The fact is that what applies generally does not apply specifically. Just as a three legged stool cannot stand when one leg is missing, diabetes cannot be effectively treated without also taking into account the cardiovascular and obesity factors.

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The main problem here, which is largely ignored by the research community, is that treating diabetes effectively adds to the short term costs and requires physicians to do something they are very uncomfortable doing - admitting they alone cannot effectively treat their type 2 patients. This problem is deepened when one considers the rising cost of healthcare. While there is little argument that a multi-disciplined approach to treating diabetes would yield long term cost savings, in the short-term costs would actually rise.

This, in essence, has always been the problem with diabetes. This is also the reason Diabetic Investor does not hold out much hope that things will change anytime soon.

Making matters even more complex is another trend that is developing in the diabetes device world. Walking the exhibit hall, it seemed as if every device company was talking about connectivity. Whether it was an insulin pump company talking about closed loop insulin delivery systems where a continuous glucose monitor communicates with an insulin pump, or a glucose monitoring company talking about monitors that automatically send readings to the physician, one thing is clear: connectivity is coming and will bring an avalanche of information.

This connectivity goes beyond glu-

To Diabetic Investor, the battle for GLP-1 supremacy comes down to two simple items, experience and delivery systems. In both areas, you have to give the edge to Amylin and Byetta LAR. Having worked in this space with the current version of Byetta, Amylin has a unique understanding of what it takes to sell physicians on GLP-1 therapy. Granted, no one would argue that Novo does not have a great understanding of the diabetes market, quite the contrary. However, deep experience in insulin sales does not necessarily translate into sales of GLP-1 therapy; a fact Amylin and Lilly learned from the mistakes they made when Byetta first came to market. As Vernon Law, a pro baseball player once noted "Experience is a hard teacher because she gives you the test first, the lesson afterward."

cose monitors and now includes blood pressure devices and scales, used in combination. These all deliver data to a third party interface which in turn has the ability to take all this data and send it on to the patient's computer, cell phone, educator, physician and/or insurance company. As with most diabetes related technology, connectivity has both promise and peril.

There is no question that the more information a patient and their healthcare team have the more effectively they can treat their diabetes. Given our belief that treating diabetes effectively requires a multiple disciplined team, having all this various data could lead to overall better outcomes and lower total healthcare costs. For example, if this data shows the patient is beginning to gain weight, it's possible the patient's healthcare team could intervene before a small problem becomes a big problem. It's also possible that if glucose data shows an upward trend,

the physicians would intervene and make therapy adjustments, again preventing a small problem from becoming more serious.

While this sounds great in theory, like most diabetes technology, the problem comes when you try and apply all this fancy technology to how patients actually live their lives in the real world. The fact is the majority of patients with diabetes live their lives with diabetes and not for their diabetes. Granted, there are a small percentage of patients who are uber users and would embrace this technology, but for most people all this effort just isn't worth it. This is true even if all this information is automatically delivered with no effort whatsoever on their part.

The main issue for Diabetic Investor isn't the technology but actually motivating the patient to gather the information. It's well known that type 2 patients fail to monitor their glucose levels on a regular basis. With all the advancements in glucose monitoring - alternate testing, no-coding, fast test results, small monitors that are easy to carry and now come in all those great colors - the average testing frequency remains below two tests per day. Someone has to explain to Diabetic Investor what the patient's healthcare team will learn from 14 data points per week. This, of course, assumes the patient is actually monitoring their levels twice a day. In the real world, it's not uncommon for patients to skip monitoring altogether.

When explaining the value of 14 data points, Diabetic Investor would also like to know how valuable this information is if the healthcare team does not know when or if the patient actually took their medication or what the patient ate or if the patient was exercising - we think you get the point here. Looking at glucose data alone is a good start, but that's all it is, a start. Making therapy

adjustments on glucose data alone is like building a puzzle without all the pieces.

As this is being explained to Diabetic Investor, can someone please tell us who's going to pay for all this data analysis? Please add an explanation of when the healthcare team will find the time to not just analyze the data, but meet with the patient to discuss what all this data means. There are many who say that software can provide the data analysis and the healthcare team could use the internet or mobile phone technology to effectively communicate with their patients. This, of course, assumes they are getting the data in the first place.

One has to wonder how receptive physicians will be to all this technology. It is not uncommon, even when the patient collects data, that their physician fails to even look at it. This is not necessarily an indictment of the physician. When you have just 10 minutes or less in front of a patient with diabetes, it's difficult to cover everything, even when you have seen the data in advance. Given time and infrastructure constraints, it's difficult under the best of circumstances to use all this effectively.

These realities will not stop companies from trying, nor should they. All they need to do is put as much investment into educating the patient as they have in developing all this wiz-bang technology. Once the patient understands that this data actually has value and will impact their lives in a positive way, the data will be collected. As Diabetic Investor has been stating for years, the reason patients don't gather data has nothing to do with how the data is gathered. The reason is they don't see any value or action step related to all this data.

One area where there is no lack of data is the GLP-1 therapy space.

Make the Connection from page 5

Amylin and their partners Lilly (NYSE:LLY) and Alkermes (NASDAQ:ALKS) are engaged in battle with Novo Nordisk over the future of whose drug is best. In typical Novo fashion, the company is building a voluminous set of data to prove that Liraglutide is better than Byetta or Byetta LAR. For their part, Amylin, Lilly and Alkermes are doing an equally impressive job of showing that Byetta and Byetta LAR should be the drug of choice.

Diabetic Investor is not going to get into this contest of who has accumulated the better data set. Nor will we engage in this tit for tat each company has offered as to why the competition's data is flawed or imperfect. Instead, we will focus on what matters most and that is the patient with type 2 diabetes. As we noted earlier, Diabetic Investor considers the GLP-1 category to be the most promising option for treating patients with type 2 diabetes. We also believe that although Liraglutide has run into some unexpected issues at the FDA, the drug will eventually be approved.

To Diabetic Investor, the battle for GLP-1 supremacy comes down to two simple items, experience and delivery systems. In both areas, you have to give the edge to Amylin and Byetta LAR. Having worked in this space with the current version of Byetta, Amylin has a unique understanding of what it takes to sell physicians on GLP-1 therapy. Granted, no one would argue that Novo does not have a great understanding of the diabetes market, quite the contrary. However, deep experience in insulin sales does not necessarily translate into sales of GLP-1 therapy; a fact Amylin and Lilly learned from the mistakes they made when Byetta first came to market. As Vernon Law, a pro baseball player once noted "Experience is a hard teacher because she gives you the

Given that all the major BGM companies are staking out their territory and parsing the market into smaller and smaller sub-markets, Intuity would make a nice addition to someone's product portfolio. Just as LifeScan has been very successful capturing insulin using patients, someone just might look at Intuity as an effective product for non-insulin using patients. The device is simple to use and, best of all, the patient does not have to carry around all the pieces of equipment of a conventional monitor. The lancet, test strip and monitor are all in one simple to operate unit.



test first, the lesson afterward."

Photo Courtesy of Intuity Medical

When it comes to delivery systems, Liraglutide actually has several compelling factors in its favor. Besides once daily administration, no one is better at designing pen delivery systems than Novo Nordisk. Liraglutide is also delivered using a conventional insulin needle and does not require any mixing by the patient. The patient simply dials the dose and injects.

Even with these advantages, it's hard to top once-weekly delivery. Yes, when Byetta LAR first comes to market, it will be delivered via syringe, require mixing and will carry a larger needle size than Liraglutide, although the needle size is not the harpoon many have imagined. Using their experience from Byetta, Amylin is already working on a simple pen delivery device which will allow the patient to simply dial out the dose and inject.

Based on these facts, the choice

becomes rather simple: a patient can inject 365 times each year or 52 times each year. This fact is so simple and easy to understand it's amazing how many people just don't get it. After talking with several endocrinologists and primary care physicians, Diabetic Investor can state that these people who will actually be prescribing these drugs get it and get it big time. They know all too well that therapy compliance is one of the biggest, if not the biggest, obstacles to achieving better control. They know from experience that patients on oral therapy options don't always take their medications and only in rare circumstances are pills difficult to administer. Just ask anyone on multiple medications or insulin plus orals what they would prefer - a therapy regimen taken every day or one taken just once a week and you'll understand why LAR could change the paradigm in treating type 2 diabetes. This may

Make the Connection continued page 7

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seem like common sense that less frequent administration is better than more frequent administration. But, when it comes to common sense and diabetes therapies, Diabetic Investor is reminded of something Ralph Waldo Emerson once said, "Nothing astonishes men so much as common sense and plain dealing."

Before we conclude this issue, Diabetic Investor would be remiss in our duties if we did not take a look at our friends in the blood glucose monitoring and insulin pump world. As everyone knows, Diabetic Investor is not overly optimistic about the future of the BGM market and we didn't see or hear anything at the conference that changed our viewpoint. However, this does not mean there are no opportunities in this space. One company that has been on the Diabetic Investor radar screen is Intuity Medical which we ran into at last year's conference. Just as a refresher course, Intuity has an all-in-one blood glucose monitor.

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Roche was the first to recognize the potential of an all in one unit when they introduced the Accu-Chek Compact into the market, as was Bayer with their Breeze meter. Both meters came with test strips attached so that all the patient had

to do was lance their finger and test. Both companies understand that one of the biggest complaints from patients about testing was all the stuff they had to carry around to perform a test. Simply put, the less equipment to carry around the better. (Not unlike something we just talked about with LAR, where less frequent administration is better than more frequent. Some people will just never learn.)

Granted, non-insulin patients do not test as frequently as insulin users. Still, this is a huge market

Sticking with glucose monitors, and yes the pun was intended, in looking at the continuous side of things, not much has changed. Medtronic (NYSE:MDT) continues to see CGM as the pathway to a closed-loop insulin delivery system while Dexcom (NASDAQ:DXCM) continues to see CGM as a way to make some money. Dexcom continues to expand their market opportunities by their willingness not to be tied to one product or therapy option. It should be noted that nearly 40% of Dexcom's customers are following multiple daily injection therapy and that Dexcom is working with both Animas and Insulet (NASDAQ:PODD). Additionally, Dexcom has a relationship with Edwards LifeSciences (NYSE:EW) for a hospital based system.

and even capturing a small percentage translates into millions of dollars. Diabetic Investor has never understood why meter companies will go to the end of earth to capture insulin users and largely ignore non-insulin users. Once again, it seems like common sense to market a meter specifically for non-insulin using patients. And, what would be better than an all-in-one device that does not require the patient to carry around a lancet device, meter and vial of test strips?

To put this more plainly, consider there are approximately 4.5 million insulin using patients while there are 10 million plus non-insulin patients. Let's say a company could capture 5% of the non-insulin market and let's further assume that these patients are typical patients who test just twice a day. Add it all up and that's nearly 400 million test strips sold each year. These patients also carry the added benefit that you most likely don't have to worry about them converting to a continuous glucose monitor in the future which eats away at your user base. Given how the major players are fighting over each share point, it's amazing that there is a whole set of patients just waiting to be catered to that are going unnoticed.

Although Diabetic Investor did not ask the good folks at Intuity if they would be willing to offer their device in fancy colors or come up with skins for their device, I'm sure this wouldn't be a huge issue and it just might make the majors sit up and take notice. After all, we all know how successful they've been by offering their monitors in fancy colors.

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Some might believe that the controversy over the benefits of intensive management would be a negative for Dexcom. Diabetic Investor doesn't see it that way. We have never viewed the primary benefit of CGM used in a hospital being improved outcomes. The fact is the most compelling case for CGM in a hospital is its effect on productivity. No matter how one views the Portland Protocol, it's clear more and more hospitals are moving in this direction. This means they soon could have a choice: have the over-worked nurse come into the patient's room every hour on the hour and perform a glucose test or the nurse could attach a CGM once which delivers readings continuously with the data steaming to the nurses' station.

If you're wondering if Diabetic Investor has a theme going here, you're right. The companies that will be successful in the diabetes market, whether it's drugs or devices, will be ones who understand that simple is better than complex. While it may seem obvious that patients and the physicians who treat them would embrace simple solutions, Diabetic Investor continues to be astonished that so many companies remain clueless. Diabetic Investor would challenge anyone to go out and ask patients, physicians, educators and hospitals these questions: Given the choice, would you prefer therapy options that are delivered more or less frequently? Or, given the choice, would you like a monitoring device that requires the patient to carry around multiple items to

perform the test or have all these items in one simple to operate unit? Then, go to the hospital and ask those over-worked nurses and the hospital administrators which they would prefer, a tool that enhances productivity or one that increases their already full workload?

Diabetic Investor has been covering this industry for many years now and we continue to be amazed at just how many very bright people can't seem to see what everyone

data, that no data will be collected. It would be equally wise to consider the burdens facing the patient's healthcare team. **As Abba Eban stated, "History teaches us that men and nations behave wisely once they exhausted all other alternatives."**

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else knows. Perhaps some good will come out of these difficult economic times, as companies see that their previous strategies just aren't working. Perhaps they will become wise to the fact that simple solutions are the pathway to success. Using history as a guide, they might just look back and understand that all this fancy technology is no good if it's not used by the patient. They might just learn that until a patient understands the value and impact of

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