JUVENILE DIABETES CURE ALLIANCE

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Organizations Mentioned:

- American Diabetes Association (ADA)
- Diabetes Research Institute Foundation (DRIF)
-JDRF
-Joslin Diabetes Center (Joslin)

Type 1 Diabetes Charitable Foundations

Update Report:

Type 1 Treatment Innovations Have Not Derived From the Non-Profits

Conclusions:

- Commercial enterprises have more effectively driven recent innovations in type 1 treatment and complications than the non-profit organizations
- Considerable funding by most of the four major type 1 non-profits (over 40% of their total type 1 research grants in 2010) is directed toward treatments and complications every year. This use of funds is incongruous with the intentions of donors who contribute for a cure
- Funding of treatment and complications research by the non-profits is less than 2% of diabetes-related research and development expenditures by for-profit enterprises
- We believe the non-profits can have a greater research impact by allocating more funding toward Practical Cure research

Managing type 1 diabetes (type 1) has always been difficult. Fortunately, management of the disease has improved for many diabetics due to innovative products that have been developed over the past several decades. The JDCA is in favor of innovation that facilitates the management of type 1 and results in a better lifestyle and improved health. This report delineates the reasons why we believe that the pursuit of these objectives is best accomplished by commercial enterprises rather than non-profit organizations.

Most people consider the discovery of insulin to be the first major type 1 treatment breakthrough. This was a life-saving event that gave people with diabetes the opportunity to live a relatively normal lifestyle. New technologies including the insulin pump, blood glucose test strips and blood glucose meters were developed in the 1960-70s and are widely used today. Technological improvements since then have further advanced the science of treatments.

The following list represents the major treatment advancements that relate only to type 1 that have been introduced since the mid-1990s; when each treatment received US FDA approval, or CE approval outside the U.S.; and the responsible party:

- Rapid-Acting Human Insulin Analogue (Humalog)---1996 by Eli Lilly[1]
- Professional Continuous Glucose Monitoring (CGM) Systems---1999 by Minimed[2]
- Long-Acting Insulin Analogue (Lantus)---2000 by Aventis Pharmaceuticals[3]
- Integrated Insulin Pump and CGM Technology---2006 by Medtronic[4]
- Insulin Pump and CGM with Low Glucose Suspend (outside the US)---2009 by Medtronic[5]

The non-profits' absence from this list of responsible parties is an indication that non-profits have not been major contributors to the development of treatment breakthroughs since the mid-1990s, a time frame that is relevant to current and future donors. In contrast, commercial enterprises were instrumental in developing all of the listed treatments. We believe that development of the key treatments introduced since the mid-1990s would have been developed with or without the non-profits' participation. It should be noted that this summary depicts the most important developments instead of listing every incremental enhancement to an existing technology.

Notwithstanding the absence of major treatment breakthroughs by non-profits in recent history, most of the four major type 1 charities allocate significant funding to this effort every year. The JDCA's analysis of their funding of treatment/complications research since the mid-1990s indicates that:

- Non-profits have not systematically driven major developments in type 1 treatments
- In 2010 the four major type 1 charities allocated an estimated 41% ($60 million) of their total type 1 research grants to treatments and complications research[6]
- A meaningful percentage of the non-profits' treatment spending is related to the development of a new device that is concurrently being pursued by a large commercial enterprise

Commercial enterprises have significant revenue and profit incentives to develop innovative diabetes treatments. Estimated worldwide revenues of insulin, diabetes devices and related consumables were $25-30 billion in 2010.[7] This market is sufficiently large to maintain the status quo and to allow for the gradual development of new treatments.

The JDCA is not opposed to the charities' sponsorship of an occasional advocacy campaign that promotes new treatments, but better treatments will not lead to a cure for type 1. As a result, we believe that **the non-profits' annual funding of significant treatment research does not comply with the intentions of donors who contribute for a cure and is inconsistent with the ubiquitous "cure" message that is conveyed to solicit contributions.**

We believe the non-profits would have a far greater impact by directing more funding toward Practical Cure research because:

- Their funding of treatment/complications research has been ineffective in systematically producing major breakthroughs in new type 1 treatments in recent years
- Large established commercial enterprises cannot be relied upon to develop a cure because a cure would inevitably shrink the revenue and profit opportunity generated by recurring diabetes product sales
- Compared to the type 1 charities, commercial enterprises have significantly larger financial resources to direct toward development of new non-cure treatments. We estimate that research and development expenditures for type 1 diabetes products by just six large public companies approximated $3 billion in 2010.[8]
- The $60 million annually directed by the non-profits toward treatment/complications research is minuscule in relation to the research and development spending at commercial enterprises and is unlikely to result in major treatment breakthroughs, in our view
- Non-profits can fill a void in the funding of Practical Cure research---an area that is meaningfully underfunded, in our opinion

Summary and Conclusion

The JDCA believes that commercial enterprises are far better suited than non-profits to pursue the development of improved products to treat type 1 and its complications. History is replete with examples of commercial enterprises introducing important treatment breakthroughs. Although some of the major type 1 non-profits direct significant funding toward treatment/complications research every year, they have not systematically introduced treatment breakthroughs in the past 15 years.

The major type 1 charities would have a greater impact if the majority of their $60 million of annual treatment/complications research funding was re-directed toward Practical Cure research, in our view. We have illustrated in prior JDCA reports that type 1 Practical Cure research is an area that is currently underfunded.[9] Allocating more resources to this research would help to fill this void and accelerate the timeline to a type 1 cure. In addition, directing more resources to type 1 Practical Cure research would better align research funding with both the intentions of donors who contribute for the reason of a cure and with the "cure" message that non-profits primarily rely upon in the solicitation of funds from donors.

[1] The Diabetes Monitor, "Lispro Insulin (Humalog)," January 6, 2010, retrieved from http://www.diabetesmonitor.com/lispro.htm.
[2]Medtronic (MDT), "Innovation Milestones," retrieved from http://www.medtronicdiabetes.net/aboutmedtronic/innovationmilestones.
[3] DocGuide.com, "FDA Approves Once-Daily Lantus (Insulin Glargine) For Diabetes," April 24, 2000, retrieved from http://www.pslgroup.com/dg/1cdef6.htm.
[4] MDT
[5] MDT
[6] Charity and Foundation Data and JDCA estimates. For funding breakdown, see the JDCA "Industry Expense Models" report dated August 29, 2011, Exhibit B: Charitable Organization Research Grant Breakdown.
[7] The JDCA estimate is based on corporate data from Eli Lilly and Company, Johnson & Johnson, Medtronic Inc., Novo Nordisk A/S, Sanofi-Aventis, as well as:
MedMarket Diligence, LLC, *Products, Technologies, Markets and Opportunities in Diabetes Management Worldwide, 2009-2018, Report D510*, July 2010, retrieved from www.mediligence.com/rpt/rpt-d510.htm.
A JDCA report "Partnering with Commercial Enterprise" dated November 3, 2011 estimated that global annual revenues for drugs, including insulin, to treat either type 1 or 2 were $34 billion in 2010, with an additional $10-15 billion in revenue generated by global sales of devices such as pumps and meters and consumables such as test strips, lancets and syringes. That combined total of $44-49 billion represents revenue from treatment for both type 1 and type 2. The estimate of $25-30 billion for the type 1 diabetes market is arrived at by subtracting the estimated revenue from drugs that apply only to type 2 diabetes from the $44-49 billion figure.
[8] JDCA estimate is based on corporate data from Becton, Dickinson and Company, Eli Lilly and Company, Johnson & Johnson, Medtronic Inc., Novo Nordisk A/S, and Sanofi-Aventis.
[9] JDCA "Type 1 Clinical Trials That Target a Practical Cure" report dated January 11, 2012 and JDCA "Type 1 Human Clinical Trial Landscape" report dated January 19, 2012.

Analyst Certification
The JDCA analyst responsible for the content of this report certifies that with respect to each organization covered in this report: 1) the views expressed accurately reflect his own personal views about the organizations; and 2) no part of his compensation was, is, or will be, directly or indirectly, related to the specific views expressed in this research report.

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