JUVENILE DIABETES CURE ALLIANCE

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Organizations Mentioned:

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

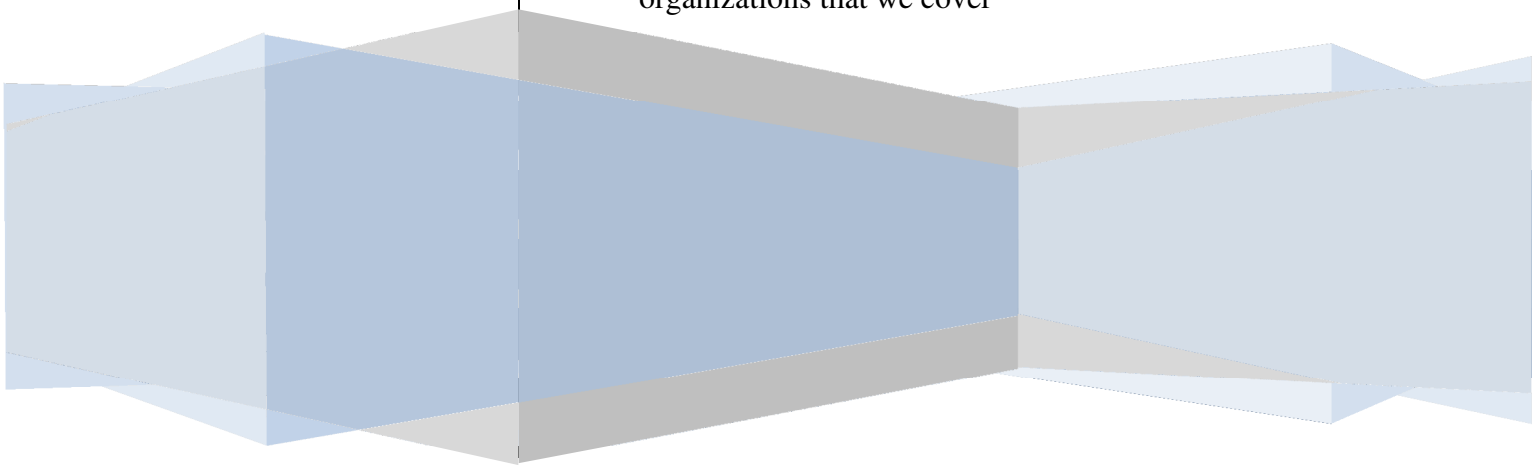
Type 1 Diabetes Charitable Foundations

Update Report:

Prevention Does Not Lead To a Cure

Conclusions:

- We believe that a prevention for type 1 will not cure individuals living with the disease, as evidenced by other diseases where this was the case
- Curing type 1 is difficult enough without hoping for this result as an ancillary outcome of prevention research or other efforts that do not specifically target a cure
- Developing an effective prevention method for type 1 could have negative ramifications for cure development, in our view
- We believe that prevention research is prevalent in the type 1 research portfolios of three of the four major organizations that we cover



Efforts to prevent type 1 diabetes (type 1) receive a great deal of attention both in the funding of research and in the messaging of some major type 1 charities. The JDCA believes there are misconceptions relating to prevention research and its relationship to the development of a cure. This report addresses those misconceptions and details why pursuit of prevention research could be detrimental to efforts to cure individuals living with type 1.

Pursuing the prevention of type 1 is a priority for three of the four major type 1 charitable organizations. The DRIF is an exception as it states that it does not fund prevention research. At least one foundation is more closely defining its identity around prevention and has stated that this is an area that will experience increased emphasis.[1]

History shows that development of a vaccine to prevent diseases does not lead to a cure for individuals already afflicted. Examining many diseases reveals overwhelming evidence that this is the case. The following is a list of diseases for which vaccines are an effective preventative but not a cure for people who already have the disease:

- Polio
- Smallpox
- Measles
- Mumps
- Rubella
- Chicken Pox
- Rotavirus
- Hepatitis A
- Hepatitis B
- HPV

Polio is sometimes cited by people in the type 1 community as a disease that has been virtually eliminated by a vaccine and could be a model for eliminating type 1. However, despite the development of an effective prevention method, there is no cure for polio or for any of the diseases listed above. Preventing these diseases through vaccination has not led to a cure for individuals who contract the disease.

No effective prevention methods have been developed for type 1 or any other autoimmune diseases. There are also no practical cures for any autoimmune disorders, with the possible exception of hyperthyroidism. The JDCA has not found any established data to support a clear correlation between prevention and a cure in autoimmune diseases. Since no autoimmune disease has been prevented, expecting a type 1 cure from prevention research is impractical and without precedent.

Developing a cure for type 1 is formidable enough without hoping for this result as an incidental outcome of prevention research. After decades of type 1 research there is no cure on the near-term horizon. The most expedient course to develop a cure is to specifically define and target a cure outcome.

By itself, prevention research is idealized research and curing established diabetics through prevention efforts is an improbable scenario. We believe the type 1 community generally shares the view that prevention efforts will not result in a cure. A JDCA survey reveals that 88% of respondents prefer that their contributions be directed to Practical Cure research instead of prevention research.[2] A small percentage of donors may wish to fund prevention research;

however, in order to be consistent with donor intentions, the type 1 charities should allocate significantly greater resources to Practical Cure research, in our opinion.

Funding prevention research diverts resources from Practical Cure research. The JDCA estimates that prevention research allocations by the non-profits exceed amounts directed to Practical Cure research, as defined by the JDCA.[3] As we have concluded in prior reports, Practical Cure research is an underfunded category as evidenced by the dearth of projects in clinical trials that could potentially meet the JDCA's definition of a Practical Cure. The JDCA believes that only five such projects are currently in human clinical trials.[4]

If a type 1 prevention treatment is introduced, then donors should beware of potentially negative consequences for cure development:

- Donor contributions and funding for cure research could subside due to declining public interest in the type 1 cause and potentially lead to an orphaning of the cohort of fully established diabetics. This is illustrated by the history of the National Foundation for Infantile Paralysis (NFIP), today known as the March of Dimes Foundation. The NFIP was the leading polio charity in the 1940s and '50s and its charitable donations reached a peak in 1954. Following the introduction of the Salk polio vaccine in 1955, charitable giving to the NFIP decreased every year for the next ten years and by 1964 donations had decreased approximately 65% from the peak. Due to diminished funding, the charity was forced to forego part of its prior mission to rehabilitate individuals suffering the effects of polio.[5]

- A preventative would cap the potential market size and the revenue opportunity for commercial enterprises pursuing cure development due to a lower rate of incidence of new type 1 cases. We believe that decreased revenue potential would restrain cure-oriented research and development spending by businesses and lead to diminished cure development efforts by the commercial sector.

Summary and Conclusion

Prevention research is being funded by and is a priority of most of the major type 1 charities that we cover. It is also garnering increased emphasis from at least one of them. Examining prevention techniques for other diseases produces no basis for the conclusion that a type 1 preventative would cure fully established diabetics. Developing vaccines for other diseases did not result in a cure for individuals that contracted those diseases. Therefore, it is improbable that a type 1 cure will develop as an incidental outcome of prevention research or other non-cure efforts.

The vast majority of donors support research because they want to cure individuals that are now living with type 1 instead of preventing it in people that do not now, but one day might, have the disease, in our opinion.

Donors also need to be aware that the development of a preventative for type 1 may have unintended negative consequences for cure efforts. Introduction of a preventative could diminish public interest in supporting the type 1 cause and also lead to decreased interest in cure

development by commercial enterprises. For several reasons, we believe that prevention research bears little relationship to the development of a Practical Cure for type 1 and could, in fact, be detrimental to cure efforts.

1. Brown, A., Shivers, J., & Close, K. (2011, January 31). Jeffrey Brewer Highlights JDRF's New Direction, Thoughts on the Cure, and Progress on the Artificial Pancreas Project. *Diatribe*. Retrieved from http://www.diatribe.us/issues/29/diabetes-dialogue.php.
2. As of 2/21/2012, 166 people were polled in an online survey conducted by the JDCA, entitled Prevention Survey. Respondents were asked to choose between Practical Cure research and prevention research. The reported data excludes a small number of responses where both answers were selected.
3. For an explanation of the JDCA's definition of a Practical Cure, see the JDCA "Defining a Practical Cure" report dated June 10, 2011.
4. JDCA "Type 1 Clinical Trials That Target a Practical Cure" report dated January 11, 2012
5. Baghdady, G., & Maddock, J. (2008, Spring). Marching to a Different Mission. *Stanford Innovation Review*, pp. 61-5. Retrieved from: http://www.ssireview.org/images/articles/2008SP_casestudy_baghdady_maddock.pdf

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