IMPROVING LIVES. CURING TYPE 1 DIABETES.

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# Policies to Accelerate Life-Changing Breakthroughs to Cure, Prevent and Treat Type 1 Diabetes and Its Complications

## JDRF 2018 Advocacy Agenda

Type 1 diabetes (T1D) is an autoimmune disease that requires intensive management 24 hours a day, 7 days a week and 365 days a year. Even with intensive management, people with T1D spend a significant portion of time with high or low blood-sugar levels, putting them at risk for emergency room visits as well as devastating long-term complications such as kidney failure, heart attacks and blindness.

Much progress has been made in the four decades since JDRF's founding, and more is on the horizon. Life-changing technologies such as continuous glucose monitors (CGMs) and first-generation artificial pancreas (AP) systems are now a reality. Next-generation therapies such as fully automated AP systems, beta cell encapsulation technologies and prevention therapies are now in human clinical trials, while groundbreaking research continues toward an ultimate cure. Through both research and advocacy, JDRF is accelerating scientific discovery, commercial development, regulatory approval and healthcare access for a wide range of T1D breakthroughs.

In 2018, JDRF advocacy can play an important role in accelerating innovation and ensuring access for all Americans. To that end, JDRF's advocacy priorities for 2018 are:

- **Invest in Innovation:** Support continued funding for the Special Diabetes Program (SDP), which provides $150 million a year in T1D research.

- **Ensure Regulatory Frameworks That Promote Innovation:** Ensure United States regulatory policies provide clear and reasonable pathways for scientific research and therapy approvals.

- **Promote Access for Life-Changing T1D Breakthroughs:** Encourage health plan policies to cover physician-prescribed T1D therapies at affordable costs and advocate for national policies that protect those with chronic diseases like T1D.

JDRF is the leading global organization funding type 1 diabetes (T1D) research, with a mission to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than $2 billion in research funding since our inception, collaborating with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D.

## I. INVEST IN INNOVATION

Multi-year, continuous funding for the Special Diabetes Program (SDP), which provides $150 million a year in T1D research through the National Institutes of Health (NIH), is a top advocacy priority for JDRF.

The SDP has accelerated the development of artificial pancreas systems, which use sophisticated computer algorithms and continuous glucose monitors to provide the right amount of insulin at the right time. The first artificial pancreas system, which became available to people with T1D in 2017, will truly transform lives; and multiple companies have next generations in development. The SDP also supports cutting-edge research that could ultimately lead to prevention and a cure for T1D, as well as new treatments and therapies for burdensome and costly diabetes-related complications.

The SDP is supporting research to drive the next generation of innovation. Congress recognizes the importance of this critical research program and continues to provide broad, bipartisan support. In the fall of 2016, 75 U.S. Senators and 356 U.S. Representatives sent letters to Congressional leaders urging support for the Special Diabetes Program; 74 of those Senators and 315 of those Representatives returned to Congress in 2017. In late 2017 and early 2018, a total of $300 million for SDP was enacted, funding the program through September 30, 2019. The SDP receives mandatory funding, not appropriations funding that Congress provides on an annual basis. JDRF also supports increasing the overall level of appropriations for the NIH as well as robust support for the Food and Drug Administration (FDA).

## II. ENSURE REGULATORY FRAMEWORKS THAT PROMOTE INNOVATION

JDRF is engaging the FDA to encourage regulatory frameworks for T1D therapies that promote continued innovation and improve public health, including:

- **Artificial Pancreas:** JDRF worked closely with the FDA to establish guidance for artificial pancreas device systems, which was finalized in 2012, and led to approval of the first insulin-dosing system in 2016. JDRF continues to work with the agency to shape regulatory expectations for next-generation AP systems including facilitating interoperability of components and the open protocol model.

- **Prevention Therapies:** JDRF is playing a leading role in a consortium seeking FDA qualification of certain T1D biomarkers, to facilitate their use in regulatory decision making and accelerate research and development of potential T1D prevention therapies.

- **Beta Cell Replacement:** JDRF hosts an ongoing educational symposium series with FDA staff focused on beta cell encapsulation technologies, which involve placing insulin-producing cells in a small medical device that is placed in the body to replace cells damaged by T1D. The first human clinical trial for such a product was approved by FDA in 2014 and multiple additional approaches are under development. JDRF also supports current research policies, put in place by the Bush Administration and updated in 2009, which provide strict ethical oversight for federal research using stem cell-based technologies in encapsulation and cell-based therapies for other diseases.

- **T1D Outcomes:** JDRF has organized the T1D Outcomes Program, with a steering committee of research and clinical organizations, who recently published a consensus statement defining outcomes for use in evaluation of T1D therapies in research, regulatory review, and healthcare reimbursement. JDRF is continuing to work with regulators to ensure the outcomes are utilized in their processes.

- **Pediatric Enrollment in Clinical Trials:** Inclusion of pediatric subjects in T1D clinical trials is important for research and development of T1D therapies, but regulatory approval for this has been challenging in some cases. JDRF is working with the T1D community to facilitate regulatory approval for the inclusion of pediatric patients in trials through education and establishment of best practices.

- **Regulatory Pathways for Other Priority T1D Therapies**: As additional priority research initiatives are developed – in areas such as restoring vision, immunotherapies, and others – JDRF will work to ensure regulatory pathways allow needed research, development, and approval.

## III. PROMOTE ACCESS TO LIFE-CHANGING T1D BREAKTHROUGHS

For people with T1D to benefit from these exciting new innovations, they need to be able to access to them. JDRF is spearheading a series of initiatives to improve healthcare access for people with T1D. JDRF is pleased to collaborate with many important allies in these efforts, including The Leona M. and Harry B. Helmsley Charitable Trust, the T1D Exchange and various diabetes clinical and advocacy organizations.

### Coverage, Affordability and Choice of T1D Therapies

- **Medicare CGM Coverage:** In early 2017, the Centers for Medicare & Medicaid Services (CMS) announced that coverage under the Medicare program would be extended to CGM devices approved by the FDA to make treatment decisions. To date, two CGM systems have received such FDA approval and subsequent coverage by Medicare. Unfortunately, the Medicare policy prohibits beneficiaries from using smart devices in conjunction with a CGM, making it impossible for them to share their glucose readings with others. JDRF calls for Medicare to cover the full range of blood glucose measurement and control devices, including those that communicate with or incorporate smart devices as an element of that system or device.

- **Artificial Pancreas Coverage:** JDRF supports broad healthcare coverage for artificial pancreas (AP) systems. The first insulin dosing system was approved by the FDA in 2016 and came on the market in 2017, with additional versions to follow. JDRF has successfully advocated to private insurers for coverage for these ground breaking devices, and now the 25 largest plans all cover them. JDRF will continue to advocate for coverage of current as well as future systems by private plans as well as Medicare. JDRF will also explore whether there are steps at the federal level JDRF can take to encourage access in Medicaid, given that JDRF is not set up to lobby at the state level.

- **Insulin Pump Choice:** People with T1D should have access to the diabetes management tools that are prescribed by their doctor and work best for them. JDRF strongly opposes health plan policies that limit choice of insulin pumps, and advocates for a competitive marketplace that fosters innovation. JDRF helps the T1D community advocate to health plans for needed pump technologies, through an online health insurance guide and advocacy resources. JDRF also supports expansion of Medicare pump coverage to include patch pumps, a change enacted by CMS in early 2018.

- **Out-of-Pocket Costs for Insulin and Diabetes Management Tools:** People with T1D can face high out-of-pocket costs for insulin and other diabetes management tools they need to survive. JDRF urges employers, health plans, and manufacturers to put in place policies that enable insulin and other diabetes management tools to be available at low, predictable out-of-pocket costs to prevent life-threatening conditions such as diabetic ketoacidosis and severe hypoglycemia. Specifically:
    - JDRF supports the practice of insurers making available to their employer customers a "preventive medicines" list, under which drugs such as insulin are made available without application of a deductible.
    - JDRF encourages employers to include coverage of preventive medicines in their benefit package.
    - JDRF also supports use of co-payments for insulin rather than co-insurance, as well as the placement of insulins on a preferred/low tier within plan formularies, which reduces out-of-pocket costs for beneficiaries.
    - JDRF also advocates for policies that require insurers to pass rebates received on pharmaceuticals to beneficiaries in the form of reduced prices.
    - JDRF also provides resources to the T1D community to help them advocate for robust coverage and choose plans appropriate for them.

- **Barriers to Improved Care:** JDRF is evaluating barriers to adoption for T1D therapies to assess other steps the organization can take to ensure the T1D community can benefit from new technologies. JDRF also supports plans for a diabetes clinical care commission to address potential federal barriers to improved care.

## Protections in Health Reform for Those with Pre-Existing Conditions

In 2017, JDRF released a set of healthcare principles and joined with other organizations representing people with chronic, serious, and life-threatening diseases to oppose legislation that violated these principles. These principles include:

- **Preserve protections for those with pre-existing conditions**: Individuals with pre-existing health conditions should have access to comprehensive health insurance at rates similar to their counterparts without pre-existing health conditions.

- **Allow young adults to stay on their parents' insurance until the age of 26**: Young adults should be allowed to stay on their parents' health insurance plan until the age of 26.

- **Prohibit yearly and lifetime dollar limits for essential health benefits (EHBs)**: Insurance companies should not be allowed to set annual or lifetime dollar limits on their spending for an individual's covered benefits.

- **Close the donut hole in Medicare Part D**: Provisions should remain in place to close the Medicare coverage gap for prescription medicines, known as the "donut hole," by 2020, which will help Medicare beneficiaries afford insulin and other needed drugs.

## Evaluation of New Therapies

- **Clinical Evidence:** JDRF collaborates with research partners to advance research evaluating the effectiveness of T1D therapies, to help provide healthcare decision-makers with adequate information to make coverage decisions.

- **T1D Unmet Need:** JDRF has commissioned new analyses of T1D healthcare data, to better understand and educate healthcare decision-makers about unmet needs in the population.

- **T1D Outcomes Program:** As discussed above, JDRF has organized the T1D Outcomes Program, which has proposed an expanded set of outcomes upon which to evaluate T1D therapies.