The R & D Tax Credit Aspects of Alzheimer's

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Charles R. Goulding, Andressa Bonafe and Charles G. Goulding discuss the research and development activities associated with treating and perhaps finding a cure for Alzheimer's disease and point out how the R & D tax credit can be used to advance treatment of this disease.

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With the aging of the baby boom generation, predictions are that coping with Alzheimer's disease will be the country's highest cost medical challenge. According to a recent study published by the JOURNAL OF THE AMERICAN ACADEMY OF NEUROLOGY,[1] the number of people with the disease is expected to triple in the next 40 years, totaling 13.7 million.

Many leading companies are engaged in research and development activities aimed at achieving an eventual cure. Federal R & D tax credits are available to support credit-eligible, Alzheimer's innovation activities.

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The Research and Development Tax Credit

Enacted in 1981, the federal Research and Development (R & D) Tax Credit allows a credit of up to 13 percent of eligible spending for new and improved products and processes. Qualified research must meet the following four criteria:

- new or improved products, processes, or software;
- technological in nature;
- elimination of uncertainty; and
- process of experimentation.

Eligible costs include employee wages, cost of supplies, cost of testing, contract research expenses and costs associated with developing a patent.

On January 2, 2013, President Obama signed the bill extending the R & D Tax Credit for 2012 and 2013 tax years.[2]

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The Alzheimer's Disease

The Alzheimer's disease is a progressive, degenerative disorder that affects the brain's nerve cells, or neurons, causing loss of memory, thinking and language skills and behavioral changes. Alzheimer's is the most common form of dementia among people above 65 years of age. It is the only condition among the six top killers in the United States for which there is no prevention, cure or treatment.[3]

There is no consensus as to what causes Alzheimer's disease. Age and genetics are risk factors, but most scientists understand that the condition is a complex result of a combination of determinants. Researchers believe, however, that understanding the hallmarks of the disease can open the way to future advancements. This approach is not limited to Alzheimer's; pharmaceutical R & D activities have increasingly refocused on understanding human-disease biology, in other words, how diseases work. The French Sanofi SA, for instance, has just hired 20 new R & D leaders to work in this field. According to Dr. Zerhouni,[4] head of Sanofi's R & D, the industry is "extremely good at toolmaking but not very good at understanding the biology."

Even though uncertainties remain, research has shown that Alzheimer's disease is characterized by a build-up of proteins in the brain tissue, which manifest in two ways: (1) plaques, clusters of the protein *beta-amyloid* that accumulate between nerve cells, and (2) tangles, aggregates of the protein *tau* that accumulate inside the nerve cells.

These hallmarks have somewhat guided the pursuit of a cure. On the one hand, researchers are investigating medications targeting virtually every point in *amyloid* processing (that generates *beta-amyloid*). They include attempts to block the two enzymes responsible for clipping the *beta-amyloid* from its parent compound *amyloid* precursor protein, namely *beta-secretase* and *gamma-secretase*. Some experimentations aim at preventing the *beta-amyloid* fragments from clumping into plaques, while others use antibodies against *beta-amyloid* to clear it from the brain. On the other hand, researchers have

Table 1.

Drugs	Mechanism	Company
Dimebon	Inhibits neuronal death, potentially by mitochondrial-mediated inhibition of apoptosis.	Medivation, Inc.
Bapineuzumab	Designed to bind and remove the A peptide that accumulates in the brain.	Pfizer, Johnson&Johnson
Solanezumab	Humanized monoclonal antibody that binds to the central region of -amyloid, acting as a neuroprotector.	Eli Lilly
Semagacestat	-secretase inhibitor.	
LY2886721	-secretase inhibitor.	
Crenezumab	Humanized monoclonal antibody against human 1-40 and 1-42 of -amyloid.	Roche Holding AG's Genentech
Gantenerumab	Human anti-A antibody that binds specifically to A plaques.	Hoffmann-La Roche
CERE-110 (Nerve Growth Factor Gene Therapy)	NGF may reduce cholinergic cell loss in Alzheimer disease.	Ceregene, Inc.
CAD106	A (1-6) immunotherapy	Novartis Pharmaceuticals Corporation
BMS-708163	-secretase inhibitor.	Bristol-Myers Squibb
AZD3480	Orally active novel neuronal nicotinic agonist with high selectivity for neuronal 4 2 nicotinic (nAChR) receptors.	AstraZeneca Pharmaceuticals LP, Targacept, Inc.
AZD1446	4ß2 nicotinic (nAChR) receptor activator.	
Alzhemed™	Designed to cross the blood-brain barrier, tramiprosate is an amyloid- antagonist.	Neurochem, Inc.
Affitope AD02	A (1-6) immunotherapy.	AffiRiS AG, GlaxoSmithKline
ACC-001	Protein: active immunization, peptide vaccine.	Elan Corporation, Janssen Pharmaceuticals, Pfizer, Inc.
AC-1204 (Medical food)	Chronic induction of ketosis to improve mitochondrial metabolism.	Accera, Inc.

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investigated methods to avoid the collapse of *tau* molecules and their twisting into tangles.

Currently, there are five FDA-approved medications to treat the symptoms of Alzheimer's. On average, they are effective for six to twelve months in about 50 percent of individuals taking them.[5] Since these drugs can only temporarily (and partially) slow the intensification of symptoms, there is still a long way to go in the discovery of a cure.

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Alzheimer's R & D

Many leading pharmaceutical companies are engaged in the pursuit of prevention and treatment methods for Alzheimer's disease. In recent years, various drugs have been tested; Table 1 presents examples of medications, underlying mechanisms and companies responsible for their development.[6]

Other Alzheimer's-Related Innovations

Alzheimer's innovation, however, is not limited to drugs. Innovation and development of new technologies for treating Alzheimer's patients are also occurring. In the U.K., a clinic recently inaugurated its own "Memory Lane," a re-creation of a 1950's street, with a traditional local pub, quaint café and greengrocers. The street displays original pieces of advertising and authentic phone and post boxes. This familiar design is expected to increase comfort, calm and foster socialization among elderly Alzheimer's patients.[7] The key will be to develop data measuring tools to evaluate the effectiveness of this designed environment. Similarly, in Rome, Georgia, Renaissance Marquis's assisted living facility, Harbor, presents 1950's décor as well as old pictures and drawings from the city's landmarks. All features of the facility aim at creating an optimal environment for patients, from flooring types, textures and furnishings, to state-of-the art memory stimulation systems, such as SimpleC.[8]

Conclusion

The expected growth in Alzheimer's incidence is one of the greatest public health challenges of our times. The absence of effective treatment and prevention methods accounts for the urgency of intensive research and innovation in this field. Federal R & D tax credits are available to support Alzheimer's innovation activities.

Endnotes

1 J. of the Amer. Academy of Neurology, available online at *www.aan.com/*.
2 American Taxpayer Relief Act of 2012 (P.L. 112-240).
3 For more information *see www.alzfdn.org/AboutAlzheimers/definition.html*.
4 *Sanofi to Refocus R & D on How Diseases Work*, Wall St. J., Feb. 14, 2013, available online at *http://online.wsj.com/article/SB10001424127887324162304578302133648383850.html*.
5 List of FDA-approved drugs is available online at *www.nia.nih.gov/alzheimers/publication/alzheimers-disease-medications-fact-sheet*.
6 For more information *see www.alzforum.org/drg/drc/*.
7 *Alzheimer's Patients Get a Trip Down Memory Lane: Care Home Recreates 1950s Street ... Including a Pub*, Daily Mail, Sep. 16, 2012, available online at *www.dailymail.co.uk/news/article-2204243/Alzheimers-patients-trip-memory-lane-Care-home-recreates-1950s-street--including-pub.html#ixzz2KtzE3gWt*.
8 Press Release: *Renaissance Marquis Retirement Village Announces Opening of New State of the Art Alzheimer's Assisted Living Addition in Rome, Georgia – The Harbor*, available online at *www.renaissancemarquis.com/pdf/The%20Harbor%20Open%20Now%20Press%20Release%20Oct2012.pdf*.

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