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Email: [redacted]

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This is in response to "Request for Information: Building A 21st Century Bioeconomy" published by "Office of Science and Technology Policy (OSTP)" in the Federal Register/Vol. 76, No.196/Tuuesday, October 11, 2011/Notices

Cancer was always present in human populations: there is evidence of cancer in our ancestors living in the Stone Age and Ancient Civilizations (Egyptians mummies e. g.). Nova days in The USA one of two people and one of seven children die of cancer. This is unbearable and puts on the society enormous psychological and economical constrains.

Clearly, as President Obama suggested development of "…**smart anti-cancer therapeutics that kill cancer cells and leave their normal neighbors untouched"** becomes a National Priority of the First Order. Obtaining a universal (not personalized) and relatively cheep cure for cancer will also have a global impact (and is in the interest of humanity as a whole).

These days the cancer research community is celebrating the 40 years anniversary of the "War on Cancer" a US National directive inaugurated by President Richard Nixon in 1971. The discovery of cancer causing and cancer driving genes and the Genome sequence led to efforts to find "smart targeted drugs" to cure cancer. However, despite the shameful hype in scientific literature and in popular press, leading oncologists have already accepted that cancer is not curable and the costly (~5 billions/per drug) "smart targeted drugs" we are using will convert cancer into a chronic "smoldering" illness with suffering and a shortened life since cancer cells quickly develop resistance to single or drug combinations. Obviously, the further costly hunt for cancer targeting "smart drugs" is a dead end and a waste of resources and patients lives and should be abandoned. But "big Pharma" and NCI supported researchers are still looking for new costly (~1 billion) smart targeted drugs (which have off-target-targets!) to which cancers quickly develop resistance and accelerate metastasis.

However I personally believe that the War on Cancer was indeed very successful and we have now the knowledge how to treat and cure cancer by combined gene therapy (CGTC). We know the cancer causing genes and the specific cell targets the genes in appropriate episomal expression vectors should be delivered. Our knowledge of such vectors (episomal plasmids, minicircles) and specific delivery vehicles is improving very fast.

During my tenure in NCI (1980-2008) I mostly worked to discover cancer genes. Based on some novel findings I suggested several novel treatments (vaccines, antibodies, and already approved drugs for other diseases (glaucoma) to slow down tumor growth. In the years 2006-2008 I proposed a new approach how to treat and cure cancer with

combined gene therapy (CGTC). Like my previous proposals this one was also rejected and I was forced to retire in 2008. A short description follows.

Combined Gene Therapy of Cancer Directed at Tumor Stem Cells and Patients Hematopoietic Stem Cells

Michael I. Lerman, M.D., Ph.D. (2006-2010)

The essence of my proposal is to use two known tumor suppressor genes expressed from episomal vectors: one delivered to cancer stem cells to suppress tumor growth, the other delivered to patients hematopoietic stem cells to boost the immune system to attack and destroy the tumor.

This cure program applies to all forms of cancer and all patients regardless of their genetic background, gender and age. It totally departs from the prevailing dogma that requires specific therapeutics with "targeted" drugs for each type of cancer, to be tailored to each individual tumor and patient background ("personalized treatment").

I know the genes (VHL and FUSI) and how to deliver and express them in the right cells.

This is a Manhattan type project but the cost will be thousand times less.

In the very near future, verily, humans may be genetically modified to carry an additional functional copy of the highly conserved gene, Fus1/Tusc2. I classify it as a Janus (two-faced) type gene that is most suited for prevention and gene therapy of cancer. On one hand it's a classical tumor suppressor gene (TSG) on the other it's a powerful regulator of the immune system. Over-expression of this gene will suppress and prevent tumor formation and boost the immune system leading to overproduction of hematopoietic stem cells (HSC) and most effector cells thus activating the immune attack on tumor cells. In addition, individuals with an extra functional copy of the gene will be resistant to immune diseases, and infectious diseases including HIV.

Sincerely,

Michael I Lerman