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Editorial
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Bringing New Systemic Anti-Cancer Agents from Test Tube to the Clinical Practice

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Editorial

Systemic treatments/agents: (Hormonal, Chemical, Immunotherapy, etc.) are important for the prevention and treatment of patients with malignant cancers. The process of bringing these agents from the time of discovery to the market for the indications of benefits/use is long and costly process. This process should be and must be kept outside the political and the commercial arenas.

Recently in the news media about former President Jimmy Carter' cancer "Cure". He was ongoing battle with metastatic malignant melanoma with lesions in his brain and liver. Nothing was mentioned of the fact that he under went surgery to remove the lesion in the liver. And the fact he underwent brain irradiation. But the public heard that he received a treatment with a newly approved immunotherapy drug called Keytruda. And of course the later great news that brain MRI scan did not show any signs of his original lesion melanoma spots nor new lesion(s).

Also, recently in the media news about the unfortunate premature lost of VP Biden son to cancer. And the fact that the President did allocated one billion US dollars for the VP to seek cure for cancers. The VP took his plane all over the USA, meeting the specialists from well known Universities/Institutions to find the magic cure. By sure accident he and his family found them selves in Hollywood, California on the second Sunday of February 2016 and they attendant the Oscar, Why not??

Three important facts where not presented to the VP. One: when former first lady Mrs. Nixon had cancer, President Nixon in about 1973-74 had a vision of and made statement and plans of: Curing Cancer by 1980, Balance the Budget by 1980, and be energy self sufficient by 1980. He ordered the establishment of Comprehensive Cancer Centers for that purpose.

Second, that in the USA only, cancers cause the premature death of more than 650,000 US citizens annually and they are ALL important to their family and to the Medical Scientists and physicians.

Third, that more than 50% of the cancers in the USA are preventable, and this is doable. To accomplish this, is by stopping:

Tobacco (all types)

Alcohol

Artificial sweetener, Aspartame

Refine white sugar

Reducing Obesity, and encouraging regular and proper exercise.

Add on proper early detection and timely screening, we will discover many in early stage(s) of cancers that are treatable and highly curable.

Beside the fact it is less time consuming and much cheaper to invite the proper researchers to the White House for two days working conference to bring their recommendations to the VP.

Many processes enter into the discovery of possible active agent. Some even by chance and others are by long process of search and research. The initial testing of the activity of an agent may vary according to type and what is known about that agent. The *in vitro* process will follow extensive *in vivo* process in animal systems when possible activity is suggested. It is a long and costly process. When activity is reported and accepted toxicities are indicated, the same intensive process may enter into the human investigation. This is also lengthy from possible acceptable and reversible toxicities,

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to many phases of re-checking activities, dosing, best dose schedule, to possible human and patient benefits.

Acceptable and reversible side effects, definite activities and possible patient's benefits as such or as compared to available standard treatment may end in the process for approval to market the agent. Most of the time, with indication to be used in patients with metastatic and incurable disease.

But the process of further evaluation will continue in many directions. The use of this active agent in combination therapy, the use in adjuvant setup *Vs*. standard therapy in patients with locally advanced disease after local treatment made them disease free, but still at high risk of recurrence.

At all time this process has to stay academic and clean research not influenced by concerned company, Institution, political entity, or other(s).

The cost of cancer care is of course now increasing and is now untenable, this is due in the most part to the significant costs of bringing new Cancer Drugs to market.

Thus the cost of the developing these new drugs and their approval and costs of further development to market must be reduced so as not to have a huge negative impact on patient care and overall health costs.

Efforts have been made to harmonize the regulatory processes in America and Europe.

But this harmonization may be in jeopardy because of the fall out from the UK referendum.

FDA commissioner Robert Califf recently stated that despite the recent events in the UK regulators need smooth and efficient systems to continue because of the global nature of the pharmaceutical industry.

There is the pro brexit view that Brexit will give the UK an opportunity to take the better regulation agenda forward faster than is possible at present through the European Union.

Ultimately post brexit efforts will have to be made to align practices in America the EU AND the UK and this will help to reduce costs of new drug development…. mutually agreed protocols will lower barriers to new drug development.

At all time the patients should be completely informed and the decision of using any agent(s) or treatment should be left completely to the well-informed practicing physicians (oncologists) and their patients.

In dealing with human lives and their health, there is absolutely no place for political and/or commercial use or abuse. Decision-making should be and must be left between the proper physicians and their patients and family.