## Personalized Medicine is not a Panacea for America



The genius of Henry Ford was in his perfection of mass production. Ford's assembly lines produced a oodles of Model T, with economies of scale, so that the cost of each car fell to a point that even those working in those lines could afford them. His method was copied by other car manufacturers and ultimately by other industries as well.

The pharmaceutical industry was one of them. The industry mass produces medicines that can be given in the same dose, frequency, and strength, irrespective of the patient's ethnicity, body weight, height, or gender. This assembly line keeps the cost of medicines below what they could have been (though Americans do pay a lot more than citizens of other countries, mainly due to marketing tactics). It is largely due to the pharmaceutical industry that the longevity of humans has increased exponentially over the past century. And, in turn, has made the pharma/biotech sector amongst the most profitable.

However, a wrinkle has shown up. Most low hanging fruits that synthetic chemistry could conjure has been picked. The industry has moved to biologics, which are more expensive to make. Nevertheless, they can still stick to the Model T paradigm. But, since science is restless, the boundaries are being pushed, and the concept of personalized medicine is now being increasingly touted.

Perhaps <u>CAR T</u> therapy best exemplifies personalized medicine. It is now routinely being proposed for cancers and even auto-immune diseases like lupus. Chimeric antigen receptor (CAR) T-cell therapy is a way to get immune cells called *T cells* (a type of white

blood cell) to fight cancer by changing them in the lab so they can find and destroy cancer cells. CAR T-cell therapy is also sometimes talked about as a type of *cell-based gene therapy*, because it involves altering the genes inside T cells to help them attack the cancer. As can be easily understood, this is individualized, <u>taking 9-14 days per patient</u>.

In principle, this would lead to better efficacy and safety as the drug is personalized to suit the genetic and phenotypic characteristics of a patient. The downside is that being personalized, it cannot be mass produced. Therefore, it is very expensive, costing up to

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at is a big problem. For vould cost \$25 billion. For only



spends approximately 20% of rugs, specially biologics. That nst excessive healthcare that restrict the price of iate the price of drugs. It will

start with a few drugs, and then expand. And where Medicare goes, so will other insurance companies. This will severely curtail the ability of pharma/biotech companies to continue charging a premium in the US. And if pharma/biotech companies cannot charge a high price for the personalized medicine drugs, they will have little incentive to develop or market them. And without commensurate payment, physicians will not be able to prescribe them.

The other problem with personalized medicine is the time it takes to make them. Unlike an assembly line, each "medicine" is made much like an expensive custom-fitted Italian suit. Not more than 2000 procedures can be done at present in the whole of US. To accommodate all Americans, every single hospital bed will have to be converted the CAR T therapy, which is impossible. Thus from a logistical point of view, it is impractical to consider personalized medicine as a potential pathway.

With these considerations, health care authorities and decision makers should look at personalized medicine carefully and pragmatically, and not be vowed by the science. Ultimately, someone will have to foot the bill. And the newly – minted Republican congress is in no mood to oblige.



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