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Perspective

Favipiravir and USA

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Introduction

Recent pandemic has caught the world unaware but its speed of spread and devastation along with fatality. Question naturally raised about how world leaders like USA and China prepared themselves for such thing. This is because the strong defence and military organisation of many developed countries. They have dedicated wing of research which investigate this kind terrorism and arrange advance preparation against these presumed dangers. COVID-19 which is influenza of pandemic proportion in not any exception. There are much furor about efficacy and availability of hydroxychloroquine but only a little is known about availability of another molecule which if available could be of great help in this hour of need. This molecule is favipiravir. It was invented as the most useful drug for bioengineered pandemics. Though it was developed by Toyama corporation of Japan, it was specially taken up by the Department of Defence of USA for its usefulness in bioterrorism era. So I searched for this drug.

Discrepancy

Wikipedia was naturally my preliminary search.

That wikipedia is not authentic was proved by my general query to the molecule, Favipiravir. Just few weeks back I saw that this drug was not approved at all by FDA. But now it says FDA in 2015 completed phase III trial. This absurd. FDA does never do trial. Hence, some vested interest is already suspected to be playing singer role. Frankly a nontruth is distributed by Wikipedia; this is however entirely changed now and no FDA status is now recorded at all, as if it was never placed before FDA and no trial was done in USA [1]. So who did it. Wikipedia reference showed an innocuous study, "a phase 3 Efficacy and Safety.

Study of Favipiravir for Treatment of Uncomplicated Influenza in Adults" - T705US316 enlisted in ClinicalTrials.gov, Identifier: NCT02026349 [2].

It is also written in clinicaltrial.gov that the safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government/FDA. Thus it's contrary to what Wikipedia writes about who does the trial.

I saw it before, this trial detail; being in drug regulatory in India I was naturally trying to find when the trial of important repurposed drug of COVID-19 started and how they address faring. The trial of Favipiravir started in 2014 and was completed in 2015. But where is approval? And where is market authorisation? Nothing, there was nothing. There is no such entry Favipiravir in whole FDA main website. It is stacked in archival section of FDA with huge documentation from where it is next to impossible to find what happened to the drug what was its fate. So I wrote to FDA twice, only to know that it is not possible to know anything because of federal confidentiality (personal communication). But they did do one mistake that they told that all records are worth sponsor and sponsor is Fujifilm. This is seriously not a fact. The trial sponsor of Favipiravir in USA was never Fujifilm which we will see later. Trial was completed. that is the information, the only substantial thing that clinicaltrials.gov could inform us. So was it cancelled or disapproved by FDA or sponsor did never applied for approval or market authorisation? There is no way to know that, unfortunately because of federal confidentiality. One MDVI, LLC was the sponsor of the trial. This company has no/unclaimed website. One mention was found in list at a website [3]. This is currently the only presence of that company at present. One manager was named in listed trial details of clinicaltrials.gov. She is Macy Guiont probably of MDVI, LLC; she is not traceable now. Send now another manager is named. She is Carol Epstein of MediVector, Inc. Though primarily MediVector, Inc was collaborator only now they are named as sponsor company in many related news materials [4].

Department of Defence (DoD), USA

In 2014 more than two years after getting a $139 million defense contract to develop a better treatment for the common flu, Boston biotech company, MediVector begun two late-stage trials on this that would involve more than 1,000 patients. Fort Belvoir, VA based Department of Defense's (DoD) Joint Program Executive Office for Chemical and Biological Defense had one Joint Project Manager Transformational Medical Technologies (JPM-TMT). He is David E. Hough. He announced on Oct. 2, 2012 [5], "Our job is to ensure we're making the most out of every dollar we spend," But unfortunately this sounds empty words when I diligently followed what happened to Favipiravir. In March 15, 2012 his department awarded a $138.5M contract to MediVector, Inc. to further develop Favipiravir (T-705), a broad-spectrum therapeutic against multiple influenza viruses, including the 2009 H1N1 pandemic virus and drug resistant influenza strains He told the contract will help bolster the protection of the Joint Forces against naturally occurring pandemic influenza and/or biologically engineered flu viruses. Again after completion of trial in 2015, MediVector Inc. had been awarded a maximum $9,135,695 modification to previously awarded contract

HDTRA1-12-C-0031 for the capability to manufacture antiviral therapeutic Favipiravir in the U.S. The modification brought the total cumulative face value of the contract to $211,303,678 from

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$202,167,983 [6].

Current Status

But after that no FDA approval, no manufacturing, no Favipiravir in market and no phase III trial on it targeting COVID-19. It just vanished. Now we see that Toyama which originally made favipiravir and gave license to MDVI, LLC/Medivector for development in USA is taken over by Fujifilm and they are developing it for COVID-19 through a phase III trial [7]. The whole thing is in such a mess that it needs urgent investigation. Moreover, the biggest unanswered question is where had the money gone.

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