Sausage Making at FDA: How Human Cancer Cells Got Into Vaccines

Sausage Making at FDA: How Human Cancer Cells Got Into Vaccines

> ***In a 2012 meeting, the FDA voted to allow the use of human fetal cells and adult human tumor cells in vaccines, despite acknowledging the many risks, including that vaccine recipients might later develop cancer.***

by **Robert F. Kennedy, Jr.**, *The Defender*, *Children's Health Defense*
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> ***"If the American people knew some of the things that went on at the FDA, they'd never take anything but Bayer aspirin."* — Len Lutwalk, FDA scientist**
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> ***"The FDA, by spinelessly knuckling under to every whim of the drug companies, has thrown away its high reputation, and in doing so, forfeited our trust." —* Drummond Rennie, deputy editor of JAMA**
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> ***"[The] honest employee fears the dishonest employee. There is also irrefutable evidence that managers at CDER (Center for Drug Evaluation and Research of the FDA) have placed the nation at risk by corrupting the evaluation of drugs and by interfering with our ability to ensure the safety and efficacy of drugs. While I was at FDA, drug reviewers were clearly told***

> ***not to question drug companies and that our job was to approve drugs … If we asked questions that could delay or prevent a drug's approval – which of course was our job as drug reviewers – management would reprimand us, reassign us, hold secret meetings about us or worse … When you are able to dig in, if you found issues that would make you turn down a drug, you could be pressured to reverse your decision, or the review would then be handed off to someone who would simply copy and paste whatever claims the company made in the summary document … I believe I also have documentation of falsification of documents, fraud, perjury and widespread racketeering, including witnesses tampering and witness retaliation."*** **– Ronald Kavanagh, Ph.D., pharmacist who reviewed medications for the FDA from 1998 to 2008**

Vaccines and related biological products advisory committee today

Today – Thursday, Dec. 10 – the Vaccines and Related Biological Products Advisory Committee (VRBPAC), which is the U.S. Food and Drug Administration's (FDA) internal panel that licenses new vaccines as "safe and effective," will meet to consider Pfizer's COVID vaccine. VRBAC will meet in one week, Dec. 17, to consider approval of the Moderna vaccine.

The damning safety studies in Pfizer's late release clinical trial data dump, and the severe (life-threatening) allergic reactions that bedeviled the vaccine's UK rollout, have raised red flags and public anxiety about the safety of the companies' mRNA vaccines. Anthony Fauci has addressed growing skepticism about COVID vaccines and the Operation Warp Speed program, by reassuring the public that "VRBPAC" is an "independent panel of leading experts" whom the public can absolutely trust to assure vaccine safety.

In order to help you make your own conclusion about how reliably VRBPAC will protect your health, I excerpt below the transcripts from the cavalier, ignorant and astonishingly unethical deliberations during the 2012 VRBPAC meeting where panelists voted unanimously to allow use of human tumor cells in vaccines. I urge you to read and make up your own mind whether you want to place your health – and perhaps your life – in the hands of these reckless charlatans and irresponsible clowns.

How FDA originally approved use of fetal cells in vaccines

FDA allows both human fetal cells and adult human tumor cells in vaccines. Both types have cancer risks. While both Pfizer and Moderna tested their mRNA vaccine using fetal cells, there are no fetal cells, cell debris or DNA in their final products.

However, according to company documents, Johnson and Johnson (Janssen) and Altimmune's COVID vaccines are manufactured in the human fetal cell line PER-C6, and thus the final vaccine products will contain cellular debris and DNA fragments from these cells. Researchers harvested these cell lines from the eyeball of an 18-week-old human fetus aborted in 1985, and then rendered them immortal by making them cancerous.

The AstraZeneca, Cansino, Gamayela, Vaxart, LongComm and Upitt vaccines are manufactured in the human fetal cell line HEK293, and thus the final vaccine products will contain cellular debris and DNA fragments from the fetal HEK-293 cell line. Scientists harvested this cell line from the kidney of a female Dutch fetus legally aborted in 1973 and then immortalized the cells by rendering them cancerous.

Normal primary cells, which are unable to replicate indefinitely, ultimately die. Immortalized cell lines are derived from known malignant cancer cells such as those obtained from Henrietta Lacks (HeLa) or created in the

laboratory by introducing viral oncogenes or chemical exposures capable of mutating normal primary cells into immortal tumor cells.

According to FDA's "The Pink Sheet" dated Nov. 29, 1999, for two decades the agency has been acutely aware of the inherent risks of using immortalized cell lines for vaccine development. The FDA CBER Director Dr. Peter Patriarca, M.D. explained that continuous cell lines are used for their ability to self-propagate, making them an ideal substrate on which to grow viruses, "the worst thing we are concerned about is … malignancy, because some of these continuous cells have the potential for growing tumors in laboratory animals."

Patriarca further conceded that "the technology to make these vaccines actually exceeds the science and technology to understand how these vaccines work and to predict how they will work." This dire "black box" conundrum that Patriarca described in 1999 is even more acute today with the urgent pressure to develop COVID vaccines before manufacturers have tested them in animals or subjected them to long-term safety studies.

We call vaccines "biologics" because vaccinologists have traditionally grown their antigens on biological substrates – usually animal tissue. Competing companies culture COVID vaccines on a variety of animal strata. The Merck and IAVA COVID vaccines are manufactured in vero monkey cells, and thus contain cellular debris and DNA fragments from vero monkeys in the final product. The Sanofi, GSK, and Novavax COVID jabs are manufactured in insect cells and thus contain insect cellular debris and DNA fragments in the final products.

Public health advocates criticize the use of animal tissues in vaccines due to risks that they carry endogenous viruses, microbes, parasites and lack safety testing. (Plague of Corruption, Mikovits 2020).The first use of human fetal cells in vaccines occurred around 60 years ago, but the practice is

increasingly popular. It was always controversial. Immunologists long considered using cells from aborted human fetuses in vaccines to be a high-risk gambit; human DNA debris is much more likely to infiltrate cells in vaccinated individuals than insect or monkey DNA.

Researchers and regulatory agencies have worried for more than 50 years about the potential for injected DNA to cause cancer. According to Dr. Theresa Deisher, a research scientist, primitive (unmethylated) DNA chains from human fetuses have the ability to 1) activate immune receptors that could lead to autoimmune attacks in susceptible individuals who have genetic predispositions that cause their own DNA to be under-methylated, or 2) insert into cells where they could combine with host DNA and cause mutations.

Regulators have in the past predicted that the odds of that happening were less than 1 in a trillion. However, in early gene therapy trials this event did indeed occur in 4 of 9 boys, 1 of whom died from the leukemia the insertions caused.

“Researchers have long observed that when introduced DNA enters a cell, it chooses a region of the cell that gives it a survival advantage. These could be the regions that are most likely to produce long-living cancer cells,” Dr. Deisher told me. FDA has never made any effort to test the safety of this practice or to determine whether the epidemic of soft-tissue cancers is “vaccine-generation” children is related to the use of cancerous fetal cells in vaccines. Even worse, in 2002, FDA green-lighted vaccine companies to use cancerous tumor cells from adults in vaccines.

FDA as an arm of Big Pharma

Before reviewing the shocking transcript of the FDA meeting that approved this dubious practice, we need to understand the conflicts and corruption that pervade this rogue agency. If we are to ever develop safe, effective COVID vaccines, we need first to stop thinking of the FDA as a regulatory agency; it

is an arm of the notoriously corrupt pharmaceutical industry.

According to a 2017 Emory University study entitled "Thick as Thieves? Big Pharma Wields Its Power with the Help of Government Regulation," FDA bureaucrats act as "enablers, or perhaps worse still, [they are] complicit in questionable or ethically unsound activity as a result of being driven by self-serving motives …." A 1992 law that allows drugmakers to buy fast-track approvals for new products from FDA has poured concrete on a regulatory dynamic already corrupted by all the ubiquitous mechanisms of "agency capture."

Between 2000 and 2010, pharmaceutical companies paid the FDA $3.4 billion to gain rapid drug approvals. Today, Pharma companies underwrite three-quarters of FDA's budget for scientific reviews (ProPublica) and fund nearly 50% of the FDA's total annual budget through PDUFA fees. In exchange, the agency increasingly fast-tracks expensive drugs and vaccines with significant side effects and unproven health benefits.

No one at FDA wins kudos for slowing down those money flows. To the contrary, according to FDA's own employees, drug company payments bias regulators, with "an inclination toward approval."

According to Dr. Michael Carome, a former Health and Human Services (HHS) official and a director of the advocacy group Public Citizen, "Instead of a regulator and a regulated industry, we now have a partnership … That relationship has tilted [the FDA] away from a public health perspective to an industry friendly perspective."

Corrupt vaccine approval panels

But as corrupt as FDA is, the internal panels – VRBAC – that approve new vaccines make the rest of the agency look like a Sunday church picnic.

When Dr. Fauci, Paul Offit, Peter Hotez and Bill Gates tell

you that you needn't worry because FDA is the "gold standard" for vaccine safety and that the ultimate licensing decision will be made by an "independent panel of experts," they are talking about VRBPAC. But VRBPAC is far from "independent." It is not even comprised exclusively of public officials. Instead, it is populated by outside "experts" who are almost all pharmaceutical industry insiders.

In 2003, following a 3-year investigation, the United States Congress's House Oversight Committee found VRBAC was completely dominated by the vaccine industry.

According to findings of the congressional investigation, VRBAC's "independent" vaccine panel members often share vaccine patents with the pharmaceutical companies whose products they are evaluating. They "own stock in those vaccine companies, receive payment from those companies for research and paid speeches. They occupy consulting lofty and powerful sinecures and accept payments to monitor vaccine trials and funding for their academic departments."

The 2000-2003 U.S. House Government Reform Committee's investigation of VRBPAC found that: (1) "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry." (2) "Conflict of interest rules employed by the FDA … have been weak, enforcement has been lax and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings … In many cases, significant conflicts of interest are not deemed to be conflicts at all."

Congressional investigators offered a typical example of the sort of financial entanglements that put VRBPAC under Pharma's slavish control. That example was the December 12, 1997, VRBPAC meeting that approved Wyeth's (now Pfizer's) rotavirus vaccine, Rotashield.

The Congressional investigators detailed the committee's cozy nepotism with vaccine makers.

> **"Examples of Conflicts of Interest:**
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> 1. "For instance, 3 out of 5 FDA advisory committee (VRBPAC) members who voted to approve the rotavirus vaccine in December 1997 had financial ties to pharmaceutical companies that were developing different versions of the vaccine.
> 2. "One out of five voting members' employer had a $9,586,000 contract for a rotavirus vaccine.
> 3. "One out of five voting members was the principal investigator for a Merck grant to develop a rotavirus vaccine.
> 4. "One out of five voting members received approximately $1 million from vaccine manufacturers toward vaccine development."

Congressional investigators concluded that, "Altogether, four out of the five committee members had conflicts of interest that required waivers, and their recommendation for approval of the vaccine was unanimous."

Here's what happened at the 2012 FDA meeting on fetal cells

HHS acknowledges that the FDA and Centers for Disease Control committees that contract and review new vaccines have historically not used "evidence-based medicine." To illustrate what this means, one only need read (below) the astonishing transcript of the 2012 panel that first approved the use of adult cancer tumor cells in vaccines.

This transcript shows what the public is never supposed to see: the behind-the-scenes sausage-making of federal vaccine approvals. Here, you will read for yourself how the "independent," "gold standard" panelists entrusted with protecting your children made monumentally consequential

decisions, not on evidence-based science, but by rolling the dice and taking what they knew was a horrendously risky bet on public health

In any other realm, this transcript would be proof of negligent homicide. The sickening side-view of VRBAC's deliberations reveals FDA's "trusted experts" for what they are; sadistic boys in lab coats giddily discussing the removal of wings from flies. We are all lab rats in their high-risk population-wide experiment. At FDA's vaccine division, that sort of reckless decision-making is routine.

In 2012, most live virus vaccines were from animal tissue and the idea of putting potentially cancerous tumor cells from adult "donors" in vaccines was still a daring and audacious gamble. That September, the FDA VRBPAC committee met to discuss this risky innovation. The transcript of that meeting – showing captive FDA officials considering a proposal by the pharma cabal to allow the use of human cancer cells (HeLa) to replace animal tissue in the manufacture of vaccines – is proof of reckless criminal conduct.

The HeLa cells are well known to cause cancer in animals, but Big Pharma wanted to lower production costs of vaccines and this method is cheaper and faster than using animal tissue for the cultivated media. The obvious question of whether such vaccines might induce cancer in recipients was on the top of the VRBPAC agenda. Health authorities and vaccine manufacturers blatantly acknowledged their uncertainty regarding the safety of vaccines made from HeLa cancer tumors as they voted to make a dangerous high-stakes gamble that would lower costs for vaccine makers

Unbelievably, FDA voted to allow pharmaceutical companies to produce vaccines using human cells without reviewing a single scientific study to determine if the outcome would be safe.

Before, I quoted some of the criminally reckless statements

from the meeting directly. A more detailed account appears in this article.

This was a full meeting of FDA's VRBPAC in 2012 to decide on the use of human tumor cell lines for the production of vaccines. I list these speakers and their titles at that time:

- Dr. Philip Krause, Acting Deputy Director of OVRR (Office of Vaccine Research and Review) and FDA's CBER (Center for Biologics Evaluation and Research). Also, Principal Investigator for Vaccine Safety: Virus Detection and Latency.
- Dr. Doug Lowy, Director of the National Cancer Institute of the NIH.
- Dr. Robert Daum, Chair of the VRBPAC.
- Donald W. Jehn M.S., Designated Federal Officer for VRBPAC.
- Keith Peden, PhD, Chief of LDNAV, DVP/OVRR/CBER.
- Dr. Marion Gruber, Director of the FDA's Office of Vaccines.
- Dr. Nathanial Brady, a self-described clinician.
- Dr. Pamela McInnes, a vaccine development expert and the Director of the Division of Extramural Research at the NIH's National Institute of Dental and Craniofacial Research, and previously a Deputy Director under Anthony Fauci at the National Institute of Allergy and Infectious Diseases.

Pharma knew that their tumorigenic vaccines might cause tumors in recipients.

Dr. Philip Krause acknowledged the risks when he said: "We have really identified three major factors that could potentially convey risk from tumor-derived cells. And these include the cells themselves … and if they were tumor-derived cells then maybe they themselves could form tumors in a vaccine recipient."

Government regulators acknowledged that tumor cell lines can

cause tumors.

Dr. Doug Lowy acknowledged this when he said: “What I think is qualitatively different about the tumor cell lines is the fact that they can cause tumors.”

FDA officials knew that tumors might occur decades after vaccination.

Dr. James Cook acknowledged this when he commented: “But certainly, if you are going to address this question about tumor risk from vaccines made in tumor cell lines, it’s going to have to be a decade’s question.”

FDA openly acknowledged that its primary objective was not to assure public safety but to help vaccine manufacturers.

Dr. Robert Daum, the leader of the meeting, commented: “ …but we are here to consider the issues that we would like to advise the agency to consider in helping the company continue the manufacturing process, what should they be concerned about, what should they be watching for.”

FDA officials knew that they could not prove vaccine safety using test animals to assess oncogenicity.

Dr. Keith Peden acknowledged this fact when he said: “I’m not optimistic that we’re going to find animal models to assess oncogenicity of DNA. That’s why I’m feeling that maybe it’s the clearance aspect that we have to deal with, with respect to DNA.”

FDA officials deliberately terminated animal safety tests too early in order to conceal consequences.

Dr. Robert Daum acknowledged this fact when he said: “Are they watching these animals long enough? Should it be longer?”

Dr. Keith Peden acknowledged this fact when he said: “Is it relevant to safety that a cell forms a tumor after a year, a

year-and-a-half?”

FDA decided to keep the tumor cell lines secret, because doctors and the public may be alarmed and say “Oh, my God!” if they knew the truth.

Dr. Nathanael Brady acknowledged this when he said: “How is this group (of vaccines) going to be able to be accepted by the consumers … As soon as you hear “a tumor-derived cell line,” how do you explain that, put the public at ease?”

Dr. Robert Daum further acknowledged these facts: “ …the practicing medical community and also the lay public. They are going to hear that we are recommending, or that the manufacturers are making, vaccines with tumorigenic cell lines and say, ‘Oh, my God,’ even if there’s no scientific basis to say, ‘Oh, my God.’”

FDA decided to use deceptive language to convince doctors and the public that the vaccines were safe even when they, themselves, were unconvinced of safety.

Dr. Philip Krause acknowledged this when he said: “… because it’s a discussion of how one communicates these issues and how the public will perceive them. But I’m not completely sure that we have a complete answer on the fundamental scientific question. So how can you communicate a scientific consensus that the product is safe unless we’re sure that you, the experts we are asking to advise us, are convinced that it’s safe?”

FDA decided to hide information about their use of tumor cells and omit it from package inserts.

Dr. Marion Gruber proposed this deception when he said: “The minute you describe something in the package insert in terms of potential clinical safety concerns, I think that really precludes using these cell substrates.”

Dr. James Cook agreed to the deception when he said: “When it

gets right down to what's in the vial and what the patient is going to ask me about, whether it's safe, I'm not going to say, well, you know, HeLa cells kill nude mice."

Dr. Robert Daum acknowledged the deception when he said: "I don't know that our charge is to micromanage the package insert today. I think that's a new discussion, with lots of issues that we haven't really aired completely."

Health authorities were skeptical about safety of the tumor lines, but they decided to subject the public to the risk, so that they could perform a global population-wide live human experiment.

Dr. Robert Daum agreed to conduct the mass human experiment with the following statement: "So I'm not sure that we can give a certainty there's no risk – don't worry about this … It's sort of a brave new world. We're all doing it together. But I think that you are doing a beautiful job."

FDA officials opted to toss the dice, perform the population-wide human experiment, and learn about the risks as time goes by.

FDA officials even cast this experiment as a noble venture in the quest for scientific knowledge. Dr. Pamela McInnes made this stunning appeal to her colleagues: "… even though there are challenges [risks to humans] to using the new technologies, they have to be embraced and we have to continue to try to learn from them and struggle through that learning curve."

In the end, FDA decided to take the risks. The leader of the committee says, "I'm a vaccine guy," then urged his cronies to approve.

Dr. Robert Daum said: "I'm a vaccine guy. They are wonderful to prevent infectious diseases … I hope that I'm speaking for everybody when I say that's the answer to your question. If not, please chime in now."

The committee formally approves the method of making vaccines from human cancer tumors.

Dr. Robert Daum said: "To come back to the agency's question of whether this committee believes it's correct scientifically to go forward with the development of these vaccines, our answer is yes."

Prior to voting to go forward, the committee made the following conclusions:

- Making vaccines with cells that are directly derived from human cancer tumors is faster and cheaper than breeding animals for the culture media.
- Millions of potentially cancer-causing vaccines will be produced.
- The vaccines may possibly cause genetic mutations.
- Millions of dollars will be made by vaccine promoters.
- The health of millions of consumers may be jeopardized.
- Information about how vaccines are made will be hidden from doctors and consumers.

This 2012 VRBPAC meeting perfectly illustrates the reckless, malevolent and murderous zeitgeist underlying the Pharma/HHS partnership. VRBPAC's "devil-may-care" decision-making allowed pharmaceutical companies to use potentially cancerous fetal cells to make millions of vaccines.

Since that meeting, vaccines containing cancerous cells and DNA strands from aborted fetuses have become pervasive among the 72 doses of vaccines that FDA has approved, and CDC "recommends" for American children. Today, the vaccines for chickenpox, MMR, hepatitis A and shingles contain fetal DNA.

There is little chance of consequence to vaccine makers from making this reckless choice, and much potential benefit. The 1986 National Vaccine Injury Act makes pharmaceutical companies immune from negligence claims and from product defect lawsuits by injured plaintiffs. Since cancer takes

years to develop, causation is virtually impossible for injured petitioners to prove in the Federal Vaccine Court where HHS is the defendant.

Furthermore, by the time a tumor develops, the three-year statute of limitations for the vaccine injury has long expired. Pharma is therefore recklessly and pathologically bold about putting carcinogens in vaccines.

Finally, it's worth considering that cancer treatment drugs like Keytruda are among pharmaceutical companies' largest profit makers. Precipitating a cancer epidemic in human populations only benefits vaccine makers' bottom line.

Remember, these are the same companies and the same FDA regulators that brought us the opioid epidemic.