

# Citizen Petition

Date: 12/6/22

The undersigned submits this petition under section **10.30** of the **FDA 21CFR10.30 Regulation** to request the Commissioner of Food and Drugs to:

- 1: Disallow all vaccine Mandates on Any Vaccines;**
- 2: Revoke Authorization for all Covid 19 Vaccines; and**
- 3: Disallow Authorization for any Newly Requested Covid 19 Authorizations.**

**I will include internet links in this petition and an equivalent reference prefix in each subsection that has references. The Reference section is at the bottom of the main section for Statement of Grounds. Please note that the references in the references section are in order by the location in this petition, top to bottom. I will also keep PDF files for most links and the information contained on my personal computer and network.**

## **A. Action Requested:**

**For FDA to:**

- 1: Disallow all Vaccine Mandates for All Vaccines; and**
- 2: Revoke Authorization for All Covid 19 Vaccines Which Includes these Links that Link to the FDA pages on those Vaccines Below, plus any Other Covid 19 Vaccines not listed; and**
- 3: Disallow Authorization for Any Newly Requested Covid 19 Authorizations.**

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**[Comirnaty and Pfizer-BioNTech COVID-19 Vaccine](#)**

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**[Spikevax and Moderna COVID-19 Vaccine](#)**

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**[Janssen COVID-19 Vaccine](#)**

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**[Novavax COVID-19 Vaccine, Adjuvanted](#)**

**Revoke All Covid 19 Vaccine Authorizations And Eliminate Vaccine Mandates**

Reference prefix for this section is M. See Ref. Section

## **B. Statement of Grounds**

### **Executive Summary of Petition**

**I am an independent vaccine researcher and have found serious problems with all Covid 19 vaccines statistically.** That is where the vaccines cause more harm than good. The mutation of the Covid 19 virus is basically being driven by immune escape from vaccine usage. Also, given all of the other vaccine problems, it is difficult to understand why vaccine mandates should ever be allowed for any vaccines.

Any vaccines authorized at the federal level in the U.S. should only be authorized with a stipulation that none of their usage can be mandated at the federal or lower levels of government or by any other individual or company. That includes vaccines like DPT, and MMR, etc.

Given the use of antivirals, antibiotics, antibody treatments, and other treatments, the mandating of vaccine usage is out of date with modern science and personal preferences of most people of the United states. In addition, given the high mutation rate of Covid 19 being caused mostly by immune escape from the use of Covid 19 vaccines, no existing Covid 19 vaccines should ever be authorized or used in the United States or anywhere else in the world, unless they are proven to substantially stop infection, viral mutation, and transmission of the Virus.

In summary I see:

**1. Dr Aseem Malhotra, a British Cardiologist has a similar view to myself and** has come to the same conclusion on Covid 19 MRNA vaccines via a different mathematical and scientific analysis. **Dr Aseem Malhotra** has published an article in the “Journal of Insulin Resistance”, “Vol 5, No 1 (2022) stating that “Covid 19 MRNA based vaccines should no longer be used”. The article is at:

<https://insulinresistance.org/index.php/jir/article/view/71/224>

**Revoke All Covid 19 Vaccine Authorizations And Eliminate Vaccine Mandates**

My analysis of Covid 19 vaccines is that the non mRNA vaccines are about as bad as the mRNA vaccines. One of the reasons that governments use vaccine mandates is related to herd rates of the pathogens. From a view of the Covid 19 pandemic, one can easily see that the vaccine mandates have caused more harm than good and that herd rates really don't apply in today's view of vaccine usage by the general population of the world. A herd rate for the Covid 19 virus only really applies with natural immunity and with no use of Covid 19 vaccines.

There should be no vaccine mandates allowed for any vaccines. Furthermore, there is a serious issue of public trust of government on health issues included in the above. Many in the health departments of the United States, especially in higher levels of management, knew or should have known about the serious problems with vaccine usage.

My petition submitted 12/6/21 to the FDA on the Pertussis vaccines outlines a strong case for revoking all Pertussis vaccines. There again, there are serious issues similar to the covid 19 vaccines; where persons primarily responsible for vaccine policy knew or should have known about the large impact and human suffering from certain vaccine usage versus the benefits of the vaccines. There are high levels of serious abuse from child hood vaccine mandates, like the grandmother at the pool with 3 grandchildren who developed Autism, where the Autism started immediately after vaccine administration to the grandchildren.

There are high level of neurological disorders most likely directly attributed to the use of the Pertussis vaccine, as outlined in my petition to the FDA to revoke all Pertussis vaccines. Getting the Pertussis vaccine where the vaccine does not cover all toxins generated by the Pertussis bacteria in my strong scientific opinion causes a serious human handicap to the human immune system for life. My Pertussis Vaccine Petition is at the government site: <https://www.regulations.gov/document/FDA-2021-P-1320-0001> . And the bulk of the deaths related to Perussis are mostly from associated Pneumonia as noted on the CDC pink book page on Pertussis – See Complications Section of: <https://www.cdc.gov/vaccines/pubs/pinkbook/pert.html>. The related deaths can be treated better with the use of antibiotics for both Pneumonia and Pertussis.

Reference prefix for this section is 1E - See Ref. Section

**2. The general problem with all Covid 19 vaccines is the mutation rate of the virus itself.** Because of the mutation rate of the virus, the efficacy of the Covid 19 vaccines drops very quickly over time. Because of the quick drop in efficacy of the vaccines, the use of the vaccines do not make up for deaths and serious injury incidents caused by use of the vaccines. Also of note in a subsequent executive summary item numbered **3**, the immune escape of the virus and mutation rate of the virus has the world's human population reliving repeated rounds of Covid 19 variant infections year over year.

That year over year reset of Covid 19 infections may last for decades rather than end more significantly in about a 3 year time frame, like a normal pandemic. Two key evaluations of viral mutation are antigenic drift and antigenic shift. The antigenic drift time frame here is generally a few months and the antigenic shift time frame is about a year, between major Covid 19 variants. The antigenic shift without vaccine use should normally be about 2000 years with an average virus. When combined with the fairly high risk factor vs the benefit of each vaccine shot, every use of a Covid 19 vaccine or vaccine booster shot has a greater chance to produce mutations and negative side effects, than it has to stop the transmission of the virus.

All values will be calculated in terms of human years of life either by life/death or via reduced quality of life. The positive value of the use of the vaccines is primarily in the short term reduction of the number of deaths: U.S. deaths from Covid 19 from start of infections to about 9/15/22 reduced by 30% =  $1,076,000 \times .7 = 753,200$ . The 30% reduction is from taking into account the average death per population in other parts of the world and adjusts for the death count in the U.S. being padded to higher numbers. The reduction in Covid 19 deaths is only relevant for about 10 months given that if one strain of the virus does not kill a more susceptible individual, another strain of the virus will come along and kill in many cases. And another reduction being applied is average efficacy over a 10 month period drops to around 0% efficacy. I also will apply a 5/10 reduction factor for this and the fact that it took about a year before the first vaccines were available. So the human years of savings from the Covid 19 vaccines is calculated at  $753,200 \times (10/12 \text{ months}) \times (5/10) = +313,833 \text{ human years}$ .

On the negative side of use of the Covid 19 vaccines there are deaths directly caused by the vaccines and serious injuries caused by the vaccines.

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I will use VAERS data from Children's Health Defense 9/16/22 data:  
[https://childrenshealthdefense.org/defender/vaers-covid-vaccines-canadian-woman-dies-bivalent-booster-shot/?utm\\_source=salsa&eType=EmailBlastContent&eId=85fe9c29-0c51-470e-a80c-39f40e1003f3](https://childrenshealthdefense.org/defender/vaers-covid-vaccines-canadian-woman-dies-bivalent-booster-shot/?utm_source=salsa&eType=EmailBlastContent&eId=85fe9c29-0c51-470e-a80c-39f40e1003f3)

which has **14,531 deaths in U.S. and 90,422 serious injuries in U.S.** The average age of death is age 72 and expected life expectancy is age 79. Whereas for serious injuries the average age of injury is age 42. I will use a 3/10 factor for the impact of serious injury versus death. And the loss of life from vaccine usage is for 7 years that being 79 -72 as noted above. And the number of years of negative impact related to serious injury is 79 – 42 or 37 years. So the negative direct impact from the use of the Covid 19 vaccines per the VAERS data is:  $(-)((14531 \text{ deaths} \times 7 \text{ years}) + 90,422 \text{ serious injuries} \times 37 \text{ years} \times 3/10 \text{ factor}) = \mathbf{-1,105,401 \text{ human years.}}$

Since the ongoing impact of the Covid 19 virus will probably go on for decades, with the high mutation rate of the virus caused by vaccine usage and immune escape, I will quadruple the negative impact of the Covid 19 vaccines to **-4,421,605 human years.** And the overall positive and negative impact from vaccine usage is **+313,833 human years -4,421,605 human years = -4,107,772 human years or 4,107,772 human years of suffering.**

In addition, it must be considered that the VAERS data is highly under reported. Therefore, the overall large number of human years lost is much larger than over 4 million human years lost.

Furthermore, another point of note related to the human years of suffering is that the number is even a larger negative number of years due to the fact that more people are dying now that were vaccinated rather than unvaccinated. This can only be caused by the build up of immune system capability from natural immunity. Naturally, an increasing usage of the vaccines reduces the protection of natural immunity.

Reference prefix for this section is 2E - See Ref. Section

**3. The benefit of the use of Covid 19 vaccines are wiped out once the viral mutations involved reduce the efficacy of the vaccines administered.** The vaccines not only cause many of the mutations but also

the pandemic gets reinvigorated over and over again probably for decades because the use of Covid 19 vaccines. Here are two videos of PHD Geert Vanden Bossche (PHD in Virology) on the issue:

<https://newsvoice.se/2022/10/dr-geert-vanden-bossche-mass-vaccination/> and <https://live.childrenshealthdefense.org/chd-tv/shows/good-morning-chd/are-vaccines-driving-virus-mutation/>

Please note that I, for purposes of this petition only need to really point out the immune escape impact from use of the Covid 19 vaccines in these videos. The immune escape dramatically increases the mutation rate of the Covid 19 virus. And that this increased mutation rate helps render the value of the use of Covid 19 vaccines not only worthless but that there is a big negative value from the use of Covid 19 vaccines since the virus will have a bigger longer term impact from more variants over time from the virus.

Reference prefix for this section is 3E - See Ref. Section

**4. If vaccine mandates were never allowed a century ago then vaccine usage would be in line with humanity's and individual values put on the use of vaccines.** That is rather than the government's health departments value put on the vaccines. We would have most likely had much more development of antivirals, antibody treatments and other treatments for disease and illnesses. We would have a much happier American population overall. And, we could have easily avoided the very large economic impact of the Covid 19 pandemic. And we would have had much less abuse of Americans that did not want to use vaccines for themselves or their children. My own investigation of vaccine policy indicates that the use of vaccines don't really save all that many lives overall nowadays. Things were much different a century ago.

**5. The world would be much better off if it had stopped working vaccine development decades ago** and gone into more antiviral research and development along with medical development like with antibody treatments and other forward looking medical development.

**6. Vaccines like the Covid 19 vaccines and most childhood vaccines only generate B memory cells and temporary antibodies.** They do not produce a balanced immune system memory like the human immune system does in a normal reaction to a typical illness involving pathogens. In other words, no T cells are being produced, that is either CD4 or CD8 T cells when vaccines are used. The T cells only come about after infection of the

pathogens. I say, we don't really know the full impact of this partial defense against illnesses like Covid 19. Here is an article on T Cell vaccines of the future, "T-cell-inducing vaccines – what's the future":

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246649/> . This link basically shows that current vaccines only deal with antibodies and B memory cells, and no other key components of the human immune system.

Reference prefix for this section is 6E - See Ref. Section

**7. The Covid 19 vaccines don't have any real benefit other than to delay onset of Covid 19 in some patients but have a high level of risk.** There are also problems with excessive risks taken by government, the medical industry, and individuals related to vaccine usage. This is excessive risk in many cases with no reward value vs the potential human cost of the risk. This is the case with Covid 19 vaccines where they have a high negative value where they cause a lot of human suffering as shown in the numbers above in item 2 of this executive summary. And, from a vaccine standpoint we should use more antibiotics, more antivirals, antibody treatments, and antiviral research and development from back in the 1960s should be greatly expanded on. I believe that all vaccine mandates should be made illegal. Many other vaccine authorizations should be revoked, also. In general, the potentially serious large problem with vaccines seems to be involved in sequences of events that in many cases take minutes to decades to play out. Many of the other diseases then acquired have lifelong effects and involve a lot of human suffering.

**I also see that we need to generally reduce the use of vaccines to allow the human immune system to develop and adapt to the requirements of individuals. I also feel that we need to do a better job of adapting to what the individual and what parents of young children want for their own health or the health of their family**

**8 General Notes:** At about the same point in time around 1950 when heavy vaccine usage started, a new field of medicine and group of doctors came about, Immunology and immunologists. Over the last seven decades we have seen about a threefold increase or more in immune system disorders and a corresponding high increase in autoimmune deficiencies. Many web references speak of various reasons why we have seen such an increase in immune system disorders. I don't believe that those references are fully inclusive of all the reasons for the increase in immune system



disorders. One cause of an increase in immune system problems is most likely heavy vaccine usage.

One note on vaccine efficacy dropping rapidly is this article on one of the latest vaccines from Pfizer: [#https://www.vaccines.news/2022-10-06-pfizer-data-covid-vaccines-negative-efficacy-30days.html](https://www.vaccines.news/2022-10-06-pfizer-data-covid-vaccines-negative-efficacy-30days.html)

MRNA vaccines are noted for often causing long Covid conditions without actually catching Covid 19 and also for subclinical myocarditis where the incidence of subclinical myocarditis is hundreds of times more common than clinical myocarditis. Covid 19 vaccines can cause serious problems with the human immune system:

[https://articles.mercola.com/sites/articles/archive/2022/11/20/micrna-covid-vaccine.aspx?ui=2acffd8702b1589da33e3653e13626139bc4a99bc57579b001e0a92b14c5edd&sd=20220514&cid\\_source=wnl&cid\\_medium=email&cid\\_content=art4HL&cid=20221121Z1&cid=DM1285819&bid=](https://articles.mercola.com/sites/articles/archive/2022/11/20/micrna-covid-vaccine.aspx?ui=2acffd8702b1589da33e3653e13626139bc4a99bc57579b001e0a92b14c5edd&sd=20220514&cid_source=wnl&cid_medium=email&cid_content=art4HL&cid=20221121Z1&cid=DM1285819&bid=)

Covid 19 can lead to blood clotting: <https://www.bmj.com/content/379/bmj-2022-071594>

Deaths related to use of vaccines are being purposely hidden by Government: [https://childrenshealthdefense.org/defender/massachusetts-death-certificates-excess-mortality-covid-vaccines/?utm\\_source=salsa&eType=EmailBlastContent&eId=ac297e18-901a-4ab3-b849-4355e5f749d1](https://childrenshealthdefense.org/defender/massachusetts-death-certificates-excess-mortality-covid-vaccines/?utm_source=salsa&eType=EmailBlastContent&eId=ac297e18-901a-4ab3-b849-4355e5f749d1) Investigations of reported Covid 19 viral deaths vs Covid 19 vaccines deaths should be reviewed for states and territories of the United States.

The FDA did get a 75 year hold of docs that should have been made available before an emergency release of any of the Covid 19 vaccines for use: <https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data>

Here is an article related to Dr Anthony Fauci and how many in the general public feel: <https://vaccines.news/2022-11-15-nuremberg-ii-mass-murder-trials-could-commence-after-midterms.html>

PHD Geert Vanden Bossche who in the end of the video with Aga Wilson linked to in item 3 of this executive summary above, believes that the existing outcome of problems from using Covid 19 vaccines was mostly

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predictable. Good virologists, others who work with bacterial research, and other medical researchers should easily come up with a list of items where Dr Anthony Fauci and government health departments knew or should have known before any decision was made to push Covid 19 vaccines. **Covid 19 vaccines should have never been developed or authorized for use.**

Deaths are now higher for those vaccinated for Covid 19 then unvaccinated - I have a PDF file of this link but the FDA should already know the facts involved: <https://www.washingtonpost.com/politics/2022/11/23/vaccinated-people-now-make-up-majority-covid-deaths/>

A lot of deaths have occurred since the start of Covid 19 vaccine development: <https://www.naturalnews.com/2022-12-02-operation-warp-speed-millions-americans-died-suddenly.html>

More and more news is coming out about deaths from heart conditions caused by use of Covid 19 vaccines:

[https://childrenshealthdefense.org/defender/autopsies-covid-vaccine-fatal-myocarditis-et/?utm\\_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51](https://childrenshealthdefense.org/defender/autopsies-covid-vaccine-fatal-myocarditis-et/?utm_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51)

**And** [https://childrenshealthdefense.org/defender/covid-vaccines-mortality-statistics-cola/?utm\\_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51](https://childrenshealthdefense.org/defender/covid-vaccines-mortality-statistics-cola/?utm_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51)

Reference prefix for this section is 8E - See Ref. Section

### **Unfavorable Notes to This Petition**

**I see no unfavorable things to this petition.** The abusive use of vaccines needs to be greatly reduced and alternate means of dealing with disease like with antivirals, antibiotics, antibody treatment and other advanced forms of medical treatment need to be developed and used more. Things like software used with medical watches or other personal devices could recognize diseases and advise on the use of antivirals or appropriate medication where warranted.

### **Conclusions**

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**I believe I have shown above that the use of any Covid 19 vaccines by humanity is way to risky and the negative outcomes are far greater than the benefits of the use of the vaccines.** In addition, because the primary preparation for Covid 19 were plans to develop vaccines rather than antivirals, the economic impact to individuals in the United States and to government has been on the order of around \$10 Trillion dollars. The bulk of the economic impact could have been avoided with much earlier advanced antiviral and other medical development.

**With the Sorrento antiviral development we very well will get a 10 fold increase in anti viral effectiveness:**

<https://investors.sorrentotherapeutics.com/news-releases/news-release-details/sorrento-therapeutics-announces-first-subject-dosed-phase-i>

I would have liked to seen antiviral development for all viruses about 2 decades ago where there was a least 3 attack vectors of the antiviral where we could currently antivirals with efficacy of about 100 times the efficacy of current generalized antivirals.

**I also conclude that all vaccine mandates should be eliminated because there are too many issues with vaccine usage.** Long term studies should have been started from day one of vaccine usage lasting hundreds of years to make sure we could see the difference between a vaccinated population and an unvaccinated population. One other problem is that without taking bad vaccines off of the market like the Pertussis and Covid 19 vaccines, every new vaccine added to the market adds too much to risk for many individuals. **It only takes one really bad vaccine to knock out all value from the use of all vaccines when vaccine mandates are allowed. And with federal law disallowing compensation from most vaccine related harm caused to people - that is another strong reason to disallow vaccine usage mandates.**

**The Great Barrington Declaration:**

[https://en.wikipedia.org/wiki/Great\\_Barrington\\_Declaration](https://en.wikipedia.org/wiki/Great_Barrington_Declaration)

is a nice start for the future of dealing with viral pandemics. That would be where no vaccines are developed or used for the virus. **Adding a 2 or better attack vector antiviral good for all viruses is a nice addition to the Great Barrington Declaration.** More advanced generalized antivirals can be used for those whose immune system don't naturally fend off some viruses. A two attack vector antiviral would be like the Sorrento antiviral above where the attack vectors are protease inhibition and disallowing viral injection into human cells. Also, the start time of the antiviral administration to an infected individual should be at a point where a good natural immunity has been established in the individual. **Added**

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technology like watch apps monitoring for viral and bacterial conditions and more generalized low cost and self administered viral and bacterial testing should also be developed.

Reference prefix for this section is C - See Ref. Section

**References Section: (Each Reference has a prefix to sections above as indicated in each section that has references.)**

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<https://insulinresistance.org/index.php/jir/article/view/71/224>

1E2. Guenther, Karl. (2021, December 15). Revoke all authorization for all vaccines containing the Pertussis vaccine components.  
<https://www.regulations.gov/document/FDA-2021-P-1320-0001>

1E3. CDC. (2021, August). Pertussis Pink Book Page.  
<https://www.cdc.gov/vaccines/pubs/pinkbook/pert.html>

2E1. Redshaw, Megan. (2022, September 23). 1.4 Million Adverse Events After COVID Vaccines Reported to VAERS, Canadian Woman Dies 7 Minutes After

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Bivalent Booster Shot. [https://childrenshealthdefense.org/defender/vaers-covid-vaccines-canadian-woman-dies-bivalent-booster-shot/?utm\\_source=salsa&eType=EmailBlastContent&eId=85fe9c29-0c51-470e-a80c-39f40e1003f3](https://childrenshealthdefense.org/defender/vaers-covid-vaccines-canadian-woman-dies-bivalent-booster-shot/?utm_source=salsa&eType=EmailBlastContent&eId=85fe9c29-0c51-470e-a80c-39f40e1003f3)

3E1. Wilson, Aga. (2022, October 9). The Dangers of Mass Vaccination During Pandemics – Dr. Geert Vanden Bossche  
<https://live.childrenshealthdefense.org/chd-tv/shows/good-morning-chd/are-vaccines-driving-virus-mutation/>

3E2. Hader, Syed. (2022, November 25). Are Vaccines Driving Virus Mutation? - Dr. Geert Vanden Bossche.  
<https://live.childrenshealthdefense.org/chd-tv/shows/good-morning-chd/are-vaccines-driving-virus-mutation/>

6E1. Gilbert, Sarah C. (2012, January). T-cell-inducing vaccines – what's the future. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246649/>

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8E2. Seneff, Stephanie. (2022, November 11). The COVID Jabs' Mechanisms of Injury. [https://articles.mercola.com/sites/articles/archive/2022/11/20/microrna-covid-vaccine.aspx?ui=2acffd8702b1589da33e3653e13626139bc4a99bc57579b001e0a92b14c5eddc&sd=20220514&cid\\_source=wnl&cid\\_medium=email&cid\\_content=art4HL&cid=20221121Z1&cid=DM1285819&bid=](https://articles.mercola.com/sites/articles/archive/2022/11/20/microrna-covid-vaccine.aspx?ui=2acffd8702b1589da33e3653e13626139bc4a99bc57579b001e0a92b14c5eddc&sd=20220514&cid_source=wnl&cid_medium=email&cid_content=art4HL&cid=20221121Z1&cid=DM1285819&bid=)

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<https://www.bmj.com/content/379/bmj-2022-071594>

8E4. Setty, Madhava, (2022, November 22) Massachusetts Death Certificates Show Excess Mortality Could Be Linked to COVID Vaccines.  
<https://childrenshealthdefense.org/defender/massachusetts-death-certificates-excess-mortality-covid-vaccines/>

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### **C.Environmental Impact**

No environmental impact expected per review of Section 25.40.

### **D. Economic Impact**

None written up here in this section per instructions for this submittal.

### **E. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Karl Guenther

(b) (6)

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