Gregory J. Glaser (SBN 226706)
4399 Buckboard Drive, Box 423
Copperopolis, CA 95228
Ph. (925) 642-6651
Fx. (209) 729-4557
greg@gregglaser.com

Ray L. Flores II (SBN 233643)
11622 El Camino Real Suite 100
San Diego, CA 92130
Ph. (858) 367-0397
Fx. (888) 336-4037
rayfloreslaw@gmail.com

Attorneys for Petitioners

UNITED STATES DISTRICT COURT OF CALIFORNIA

EASTERN DISTRICT - SACRAMENTO

Joy Garner, individually and on behalf of The Control Group; Joy Elisse Garner, individually and as parent of J.S. and F.G.; Evan Glasco, individually and as parent of F.G.; Traci Music, individually and as parent of K.M. and J.S., Michael Harris, individually and as parent of S.H., Nicole Harris, individually and as parent of S.H.,

Petitioners,

v.

DONALD JOHN TRUMP, in his official capacity as PRESIDENT OF THE UNITED STATES OF AMERICA,

Respondent.

Case No.:

PETITIONERS' REQUEST FOR JUDICIAL NOTICE, APPENDIX NUMBER THREE

TABLE OF CONTENTS **Page**

TO THE COURT, RESPONDENT, AND RESPONDENT'S COUNSEL OF RECORD:

PLEASE TAKE NOTICE that Pursuant to Federal Rule of Evidence 201, Petitioners in the above-entitled action hereby request the Court take judicial notice of the following readily verified facts, authorities, and attached documents, in support of Petitioners' Petition for Declaratory and Injunctive Relief. This motion is submitted together with Petitioners' concurrently filed Notice of Motion and Motion, Memorandum of Points and Authorities, and Declaration of Counsel.

INTRODUCTION

Since the inception of the 1986 National Vaccine Injury Compensation Program, the pharmaceutical industry started to offshore the manufacturing of vaccines. It did so to meet the growing demand in producing hundreds of millions of doses each year for the United States vaccination schedule that had quadrupled in size and scope. First, the vaccine makers harvested active pharmaceutical ingredients from Asia; then outsourced research and development. Over the past decade, the world's top five vaccine manufacturers built plants in China.

The initial leverage of the foreign supply chain turned into a reliance to reap the benefits of *globalization,* in part, enabling pharmaceutical companies to remain competitive, as well as build inroads into new markets. Over that span, United States policymakers raised few concerns about the vulnerabilities of overseas manufacturing, while doing little to address that dependency or assess the geopolitical risk that comes with down markets, conflicts, or times of war.

In this PRJN3 covering foreign supply chain issues, we bring clarity to the scale of the problem and the national security risks they pose to the Nation.

The judicial notices establish vaccines are indeed being made and imported from China into the United States. We outline the issues with the U.S. import process, the gaps in the Food & Drug Administration (FDA) inspection and monitoring programs, and the risks of outsourcing critical medicines from China. Only recently has the U.S. Congress began to identify the gaps and risk that threaten the pharmaceutical vaccine supply chain. Only when the global pandemic of COVID-19 shutdown China in January, did the FDA, news media, and federal representatives see the full scope of the offshore vaccine making problem.

The second half of PRJN3, maps the United States' overreliance on deferring some of its national security issues, related to vaccinations, to the World Health Organization (WHO). Again, the global outbreak and shutdown of nations and foreign supply chains exposed many of those vulnerabilities. Ensuing sections highlight the vaccine making processes and infrastructure that overwhelm the FDA's capacity to effectively provide quality control of vaccines, from point of origin to point of delivery. Several judicial notices reveal the lack of transparency, the "scandals" and defect recalls that plague Chinese and foreign vaccine manufactures.

The final section, reveals the WHO encroaching into U.S. policy on vaccines. It includes the WHO's participation in the planning and financing of the "release of a lethal respiratory pathogen" in autumn 2019 with its new unit in the Global Preparedness Monitoring Board. In that boardroom, the head of the Chinese Communist Party's director-general of China's CDC sits across the planning table from the director of the U.S. National Institute of Allergy and Infectious Disease.

REQUESTS FOR JUDICIAL NOTICE

1. Vaccines Being Imported From Overseas Into the United States

A. Vaccines From China

Introduction

On March, 22, 2018, the Office of the United States (U.S.) Trade Representative released a "Notice of Determination and Request for Public Comment Concerning Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices," (Docket No. USTR-2018-0005). On page 15 of the USTR Notice, the second page of the Annex, the 8-digit code No. 30022000, "Vaccines for Human Medicine," establishes that the U.S. imports vaccines from China.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the United States of America imports certain vaccines for human medicine from China.'

Citation: Office of the United States (U.S.) Trade Representative, "Notice of Determination and Request for Public Comment Concerning Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices," (Docket No. USTR-2018-0005) (2018).

https://ustr.gov/sites/default/files/files/Press/Releases/301FRN.pdf (accessed June 15, 2020). See Exhibit 419.

B. Production Overseas - Vaccines Licensed for Use in the United States

Introduction

The Food and Drug Administration (FDA) list of vaccines products by description and trade name are kept up-to-date. The 5-page product list of FDA-approved vaccines that are produced overseas, include for example influenza biologics, measles vaccines, and a broad range of vaccines from tetanus and diphtheria to cholera and zoonotic.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'many vaccines for consumption in the United States of America are produced outside of the United States of America.'

Citation: FDA (2020). Vaccines Licensed for Use in the United States. *Vaccines, Blood & Biologics.* https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (accessed June 21, 2020). See Exhibit 355.

2. U.S. Import Process for Vaccines

A. Importing CBER-Regulated Products into the United States

Introduction

The standards to import vaccine products are regulated by FDA's:

> "Center for Biologics Evaluation and Research (CBER). CBER regulates biological and related products, including blood and blood products (which includes certain kinds of devices), vaccines, allergenics, tissues, and cellular and gene therapies….
>
> - "The product must meet FDA's regulatory requirements…
> - "The Division of Case Management (DCM) within CBER's Office of Compliance and Biologics Quality (OCBQ) directs and coordinates CBER's import program…
> - "Section 801 of the Federal Food, Drug, and Cosmetic Act (21 USC 381) sets out basic standards and procedures for FDA review of imports under its

jurisdiction…

- "The FDA Product Code, a seven character set of letters and numbers, which for vaccines start with industry code "57" helps FDA classify and review imports."

The FDA tracks and monitors "biologic" imports, has an Entry Refusal Program. The FDA generates an Import Refusals Report (IRR) to "detain regulated products that appears to be out of compliance with the Food, Drug, and Cosmetic Act. The IRR "specifies the nature of the violation to the owner or consignee."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the standards to import vaccine products from outside the United State of America are regulated by the FDA'.

Citation: United States Food and Drug Administration, Importing CBER-Regulated Products Into the United States, https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/importing-cber-regulated-products-united-states (accessed October 18, 2019). See Exhibit 420.

B. FDA Product Codes For Importing CBER-Regulated Products

Introduction

"The FDA Product Code, composed of a seven-character set of letters and numbers, helps FDA classify and review imports. An FDA Product Code has five parts:"

- **Industry Code –** begins with "57"
- **Class Code –** groups the product as a "viral vaccine" or other
- **Subclass Code –** describes how the product will be used in the U.S.
- **Process Indicator Code –** "CBER-regulated products do not have a Process Indicator Code so in an FDA Product Code for a CBER- regulated product, this part is filled in with a hyphen (-)."
- **Specific Product Code –** is two numbers that "describes the particular kind of product, e.g., rabies vaccine."

An example of a product code for vaccines that are "licensed, approved, or cleared by CBER, the tables identify the Industry Code, (57), the Product Class (e.g., C [Viral Vaccines]), the Specific Product Code (e.g., 02), the product (e.g., influenza virus vaccine), trade name (e.g., Flumist), and the sponsor's (usually the manufacturer's) name, (e.g., Medimmune)."

The product code enables the FDA to quickly identify products that need import review, clearance, or refusal, as well as search databases for traceable audit trails, conduct inventory, seasonal trend analysis, and more.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the FDA utilizes product codes to import vaccine products from outside the United State of America'.

Citation: United States Food and Drug Administration, FDA Product Codes For Importing CBER-Regulated Products, October 10, 2018 https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/fda-product-codes-importing-cber-regulated-products (accessed March 30, 2020). See Exhibit 421.

C. Entry Screening Systems and Tools

Introduction

> "Automated systems help FDA employees speed their review of import entries while targeting FDA resources on the riskiest products. These systems electronically review your entry and flag risky products or entries that are incomplete or contain inaccurate data. If each line of an entry is properly submitted, a lower-risk product may be allowed to enter domestic commerce without further FDA review."
>
> - "When a system flags an entry for having incomplete or inaccurate data, FDA reviewers may ask for more information or request physical exam or sampling….
>
> - "PREDICT (Predictive Risk- based Evaluation for Dynamic Import Compliance Targeting) is a risk-based analytics tool FDA uses to electronically screen all regulated shipments imported or offered for import into the U.S.A."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that (a) 'the FDA utilizes product codes to import vaccine products from outside the United State of America', and (b) 'FDA utilizes digital analytics software on the U.S. side of vaccine imports from China.'

Citation: United States Food and Drug Administration, FDA Entry Screening Systems and Tools, December 12, 2017, https://www.fda.gov/industry/import-systems/entry-screening-systems-and-tools (accessed March 30, 2020). See Exhibit 422.

3. FDA Inspections In China

A. FDA Onsite China Office

Introduction

In November 2008, the FDA established a *China Office.*
"The mission of the Beijing-based office is to help ensure the safety, quality, and effectiveness of medical products and food produced in China for export to the United States."

The FDA China Offices objectives are:

- "Promoting international health policy harmonization and regulatory convergence;
- "Engaging with regulatory authorities, industry, academia, multilateral organizations, non- governmental organizations, and other relevant institutions to increase the FDA's understanding of China's regulatory framework and processes and share information about FDA science-based regulations and requirements;
- "Conducting risk-based, commodity-specific inspections to meet the requirements of FDA legislative mandates; and
- "Monitoring and reporting on regulatory trends, conditions, and emerging public health events that have the potential to impact the safety of FDA-regulated goods produced in China intended for U.S. consumption."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the China Office of the FDA, "China ranks second among countries that export drugs and biologics to the United States."

Citation: United States Food and Drug Administration, Global Operations - China Office, January 28, 2020, https://www.fda.gov/about-fda/office-global-operations/china-office (accessed March 23, 2020). See Exhibit 423.

B. FDA China Office Focus on Product Safety

Introduction

By year four of the FDA China Office,

> "Christopher Hickey, Ph.D., who leads FDA's 13-person staff in China, says the agency has trained more than 1,600 manufacturers and regulators on United States safety standards over the past two years."

Past Problems:

- "Some consumers have been wary of products made in China since a series of safety scares in 2007 and 2008.
- "That's when contaminants in the blood thinner Heparin, pet food, toothpaste, seafood, and other products caused illnesses and some deaths in the United States and other countries.
- "The Chinese also suffered the consequences of contaminated products.
- "In 2008, about 300,000 Chinese babies were sickened and six died from infant formula contaminated with the toxic chemical melamine, which is used to make concrete and plastics."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'China's supply chain of products to the United States of America creates complex national security concerns.'

Citation: United States Food and Drug Administration, FDA's China Office Focuses on Product Safety, March 2012, https://www.fda.gov/consumers (accessed June 15, 2020). See Exhibit 424.

C. U.S. FDA Compliance in China and India

Introduction

In preparing for an inspection with the FDA, the agency provides a list of items that the vaccine manufacturers will need, including documentation. Unfortunately, the FDA isn't permitted

to conduct "unannounced" inspections as the agency does in the U.S. Instead, the "China Food and Drug Administration (CFDA) will be conducting unannounced inspections of drug and medical device facilities beginning September 1, 2015."

> "A second problem emerged in 2015: "… Difficulties with visa applications have prevented the full number of FDA investigators, both domestic and US-based, from taking on their roles. The FDA has indicated that they are working foreign counterparts to resolving the difficulties causing the cooperative arrangements to move forward."
>
> "The U.S. Congress ordered the FDA "to increase its inspection of both foreign and domestic pharmaceutical and medical device facilities."
>
> "Knowing the Rules:
> - "FDA investigators are likely to examine many different elements of a company's facility, operations and records. According to FDA's website, the GMP Inspection Checklist includes the following":
>
> 1. "Buildings and facilities
> 2. "Equipment and utilities
> 3. "Qualifications of personnel
> 4. "Raw materials
> 5. "Production processes and procedures
> 6. "Laboratory controls
> 7. "Records and documentation
> 8. "Labeling
> 9. "Complaint management documentation
> 10. "Failure Investigations and change control
>
> "The Importance of Documentation:
>
> - "Raw materials and primary packaging materials
> - "Disposition of rejected materials
> - "Manufacturing of batches, documenting the following:
> - "Finished products, documenting the sampling, individual laboratory controls, test results and control status
>   - "Lots and quantities of materials used
>   - "Processing, handling, transferring, holding and filling - Sampling, controlling, adjusting and reworking
>   - "Code marks of batches and finished products
> - "Qualification of personnel
> - "Training records
> - "Standardized Operating Procedures (SOPs)"
>
> *Request for Judicial Notice*

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'FDA's inspection of Chinese facilities producing vaccines is less thorough than United States facilities producing vaccines.'

Citation: United States Food and Drug Administration, US FDA Compliance in China and India: How to Prepare for a GMP Inspection, 2015, https://www.ulehssustainability.com/wp-content/uploads/2018/05/ulewp15-fda-increases-presence-in-india-and-china-2017-final.pdf (accessed June 15, 2020). See Exhibit 425.

D. FDA Halts Imports from China's Huahai Chuannan Plant

Introduction

In September 2018, the FDA stated:

> "It will no longer allow imports of drug ingredients or medicines made with ingredients produced at China's Zhejiang Huahai Pharmaceuticals Chuannan factory, after a recall of one of its drugs that contained a probable carcinogen. The Chinese bulk manufacturer of the high blood pressure treatment valsartan recalled the product from consumers in the United States in July because an impurity linked to cancer had been detected."

The FDA halted China imports due to:

- After it found major manufacturing process issues during its inspection of Huahai's plant.
- FDA needed to determine how the impurities were introduced to improve the plant's quality control systems.
- The plant makes bulk ingredients for drugmakers
- FDA found N-nitrosodimethylamine, or NDMA, which is classified as a probable human carcinogen, in its valsartan.

In general, "the FDA often redacts product-specific information in inspection reports, and the report released last week did not mention valsartan, NDMA or NDEA. However, the FDA wrote that Huahai's "change control system to evaluate all changes that may affect the production and control of intermediates or Active Pharmaceutical Ingredients (APIs) is not adequate."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the Chinese drug supply chain extends far from the manufacturer's plant to the sourcing of material and ingredients.'

Citation: Reuters, Corrected (Official) Update-3: FDA Halts Imports from China's Huahai Chuannan Plant, September 28, 2018, https://www.reuters.com/article/huahai-pharm-imports/corrected-update-3-fda-halts-imports-from-chinas-huahai-chuannan-plant-idUSL2N1WE0XO (accessed March 31, 2020). See Exhibit 426.

E. U.S. Risky Reliance on China's Pharmaceutical Products

Introduction

"As of 2018, China ranks second among countries that export drugs and biologics to the United States by import line (13.4 percent). An import line is a distinct regulated product within a shipment through customs. A single shipment may include multiple lines of varying sizes. Approximately 83 percent of these Chinese import lines for drugs and biologics were human finished dosage forms (finished drugs) and 7.5 percent were active pharmaceutical ingredients (APIs)."

FDA Risk Countermeasures include:

- Deploy its risk-predictive screening system called PREDICT

- PREDICT = Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting

- PREDICT screens and analyzes
  1. Past inspection results
  2. intelligence data
  3. Extreme weather threats that could spoil a shipment
  4. FDA entry reviewers will score risk on every import line.

- FDA maintains global vigilance on higher risk facilities

- FDA works closely with international regulatory partners in Europe to avoid duplication of inspections

- FDA prioritizes drug manufacturing surveillance inspections based on:
  1. Facility's compliance history
  2. Recall trends
  3. Time since last inspection
  4. Inherent risks associated
  5. Risk Score

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that "FDA quality control programs suffer gaps, from inventory and source material ingredients, to inability to inspect plants unannounced or has complete visibility over a Chinese plant's total supply chain."

Citation: United States Food and Drug Administration, Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products, July 31, 2019, https://www.fda.gov/news-events/congressional-testimony/exploring-growing-us-reliance-chinas-biotech-and-pharmaceutical-products-07312019 (accessed March 31, 2020). See Exhibit 427.

F. China's FOIA Forms for FDA Inspections – Chinese Form 483s

Introduction

> "Through the use of FOIA (Form 483s are not generally released publicly by FDA), *Focus* found that more than 80 Form 483s were issued to Chinese manufacturers in 2015 after 132 inspections by FDA staff. The 132 inspections is only 15 more than the number conducted in 2014, but up significantly from the paltry 19 inspections conducted in 2007, according to FDA."

China's Form 483 in use:

> "Currently, 41 pharmaceutical manufacturing sites in China and five in Hong Kong are included on FDA's import alert list, which is a list of all the sites banned from shipping products to the US. China's Zhejiang Hisoar Pharmaceutical is the most recent addition (from 20 January) for good manufacturing practice deficiencies."

FDA Concerns about Form 483:

> "But there are major differences between how FDA operates in the two countries, which collectively account for about 80% of the world's APIs. Unlike in India, it's become increasingly difficult for FDA to obtain visas for its inspectors in China and in 2014, FDA closed two of its offices in Shanghai and Guangzhou, China, and consolidated operations at its Beijing location….
>
> "Concerns over how FDA can adequately track the drug and API supply chain is starting to worry Congress….
>
> "FDA also found that the Qilu site failed to follow batch manufacturing instructions and lab control procedures, in addition to questions about the facility's design…
>
> "FDA inspections at sites for Hangzhou Huadong Medicine Group Kangrun Pharmaceutical Co., Ferring Pharmaceutical, and Shanghai Desano Chemical Pharmaceutical Co. also revealed data integrity questions, particularly around the

control of computer and software systems, incomplete lab records of instrumentation calibration and sampling plans not based on scientific principles."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Regulatory Focus, "As the US becomes increasingly dependent on Chinese and Indian active pharmaceutical ingredient (API) and drug manufacturing, a deeper look into the inspection reports from the US Food and Drug Administration (FDA) in China reveals a number of question marks that parallel the same sort of issues found in Form 483s issued after inspections in India."

Citation: Regulatory Affairs Professionals Society (RAPS), U.S. FDA Inspections in China: An Analysis of Form 483 From 2015, February 10, 2016, https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/2/us-fda-inspections-in-china-an-analysis-of-form-483s-from-2015 (accessed June 15, 2020). See Exhibit 428.

G. U.S. Dependence on Pharmaceutical Products From China

Introduction

In August 2019, he Council of Foreign Relations (CFR) has "concern about a disruption in the supply chain could explain why the tariffs on Chinese products by the USTR in May 2019, worth approximately $300 billion, excludes 'pharmaceuticals, certain pharmaceuticals input, and select medical goods."

Concerns raised by CFR include:

- Safety and efficacy of Chinese made pharmaceuticals
- In 2018, one of China's largest vaccine makers sold at least 250,000 substandard doses of vaccine for diphtheria, tetanus, and whooping cough
- Latest in slew of quality control scandals caused by poor quality biologics made in China
- In 2008, contamination of raw ingredients imported affected blood thinner Herapin, caused 81 deaths in the U.S.
- Manipulation of quality data is "still endemic Chinese pharmaceutical firms."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the Council of Foreign Relations recommended expanding FDA inspections in China while also searching for other foreign sources to supply active pharmaceutical ingredients and manufacturers outside China, such as India.'

Citation: Council of Foreign Relations, U.S. Dependence on Pharmaceutical Products From China, August 14, 2019, https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china (accessed March 31, 2020). See Exhibit 429.

H. Coronavirus Disruption to FDA Inspections in China

Introduction

Due to the outbreak of the COVID-19 epidemic in China, the FDA suspended inspections of vaccine manufacturers' plants until further notice.

From FDA joint statement (2-25-2020) made by FDA Commissioner Stephen M. Hahn and FDA Associate Commissioner for Regulatory Affairs Judith A. McMeekin, they wrote:

> "Earlier this month, the FDA outlined its supply-chain surveillance plan in the wake of the coronavirus (COVID-19) outbreak in China, including the steps the agency is taking to mitigate potential shortages and supply disruptions of products from China and how the agency is handling inspections of manufacturing facilities in China… While we are not able to conduct inspections in China right now, this is not hindering our efforts to monitor medical products and food safety… We continue monitoring the global drug supply chain by prioritizing risk-based inspections in other parts of the world. The FDA is not currently conducting inspections in China in response to the US Department of State's Travel Advisory to not travel to China due to the novel coronavirus outbreak."

How will the FDA onsite inspections in China get back on track when the COVID-19 pandemic is over? The FDA said, "where appropriate," it will:

- Request records from firms "in advance" or
- "In lieu of" drug-surveillance inspections in China
- Such record will help the FDA resume onsite inspections
- Applying the use of digital records into FDA risk-based software program
- It will then prioritize inspections on those plants deemed most needed

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'COVID-19 has disrupted inspections of vaccine manufacturing plants in China'.

Citation: Drug, Chemical & Associated Technologies Association (DCAT), FDA Updates Plan for Manufacturing Inspections in China in Wake of Coronavirus Outbreak, February 27, 2020, https://dcatvci.org/pharma-news/6373-fda-updates-plan-for-mfg-inspections-in-china-in-wake-of-coronavirus-outbreak (accessed March 23, 2020). See Exhibit 430.

4. Outsourcing Vaccine Risk In China

A. U.S. Congress on U.S. Pharmaceutical Supply Chain

Introduction

Prior to the COVID-19 outbreak, the Congress held a hearing in which,

> "…lawmakers expressed alarm, and sometimes disbelief, at the lack of oversight the FDA demonstrates over these foreign suppliers—despite the fact that U.S. drug firms are continuously outsourcing their manufacturing needs."

Congressional Issues with Supply Chain:

- "'There's a hidden health crisis in this country that will affect us all,' Rep. Anna Eshoo of California, chair of the Health Subcommittee, said in the hearing.
- "The crippling inadequacy of the American drug supply….
- "FDA maintains a "catalog" of foreign manufacturers, the sites are not required to tell the FDA whether they actually make APIs and in what quantities, according to Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA. "

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'American lawmakers have called for legislation that would order U.S. pharmaceutical companies to prove where they source overseas vaccine ingredients'.

Citation: Newsweek, Congress, Grappling With Tainted Chinese Drugs, is Baffled by Lack of FDA Oversight in U.S. Pharmaceutical Supply Chain, October 30, 2019, https://www.newsweek.com/congress-spooked-tainted-chinese-drugs-eyeing-pharmaceutical-supply-chain-1468753 (accessed November 29, 2019). See Exhibit 431.

B. Coronavirus: All FDA Inspections Of Chinese Manufacturing Facilities Come To Screeching Halt

Introduction

"The US agency has suspended all routine surveillance inspections in China through the end of March because of coronavirus fears, commissioner Stephen Hahn announced late on 14 February. Despite expecting medical product shortages, Hahn said the agency is being proactive: 'We are not waiting for drug and device manufacturers to report shortages to us' before acting."

The Impact of the Pandemic:

- Roughly 90% of canceled February inspections were routine surveillance audits,
- 10% – including high-risk for-cause inspections – won't take place until March at the earliest.
- FDA expects supply chain disruption and shortages
- Interfere with supply chains
- "including potential disruptions to supply or shortages of critical medical products in the US," stated FDA Commissioner Hahn.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the FDA is monitoring China's vaccine manufacturing situation remotely from the United States'.

Citation: Medtech Pharma Intelligence, Coronavirus: All FDA Inspections Of Chinese Manufacturing Facilities Come To Screeching Halt, February 14, 2020, https://medtech.pharmaintelligence.informa.com/MT126258/Coronavirus-All-FDA-Inspections-Of-Chinese-Manufacturing-Facilities-Come-To-Screeching-Halt (accessed June 14, 2020). See Exhibit 432.

C. FDA Halts Overseas Inspections of Drugs and Devices, Citing Coronavirus

Introduction

"The agency said the spread of the virus globally prompted its decision. It had already pulled back from China, but this move will also affect India, a major generics manufacturer."

Pandemic Ripple Effect:

- FDA pulled back its inspectors from China
- China is the largest source of raw ingredients for many drugs, like aspirin, ibuprofen and penicillin
- FDA monitoring the nation's drug supply chain, identifying several drugs that could face shortages if the epidemic in China and elsewhere lasts for months.
- FDA identified "at least one drug is currently in short supply in the United States because of difficulties related to the coronavirus, but has not said which one."
- "Hospitals have struggled for years with hundreds of shortages of essential medicines, many of them generic products made overseas."

"The FDA has a staff of about 200 investigators who conduct overseas drug inspections, according to testimony before a House committee in December by Janet Woodcock, the director of the agency's Center for Drug Evaluation and Research. Most of those inspectors are based in the United States and travel around the world to conduct anywhere from three to six inspections per year. Of those, about 12 are based in foreign offices overseas, including in China."

The coronavirus further exposed one other major issue with vaccines and drugs made in China: There is no audit trail back to the supply sources.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the NY Times: "Although there is no formal tracking of where active ingredients for drugs are made, experts have estimated that about 80 percent of such materials used in American drugs are made in India or China."

Citation: New York Times, FDA Halts Overseas Inspections of Drugs and Devices, Citing Coronavirus, March 10, 2020, https://www.nytimes.com/2020/03/10/health/drug-inspections-fda-coronavirus.html (accessed March 23, 2020). See Exhibit 433.

D. FDA Anticipates Disruptions, Shortages as China Outbreak Plays Out

Introduction

"The FDA is bracing for drug and medical supply shortages in the U.S. as the COVID-19 outbreak from China continues to spread globally. The agency has contacted hundreds of drug and devicemakers, and, so far, the links of the supply chain have held but will take all available measures if disruptions appear."

FDA Commissioner Hahn noted:

- "It's worth noting that there are no vaccines, gene therapies, or blood derivatives licensed by the FDA that are manufactured in China…
- "Raw materials used in manufacturing do come from China and other locations in Southeast Asia…
- "We are in contact with biologics manufacturers to gauge any supply concerns regarding raw materials….
- **"**FDA estimates that only about 10% of pending inspections are for cause."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the FDA anticipates disruptions and shortages of vaccines due to Covid-19'.

Citation: Fierce Pharma, FDA Anticipates Disruptions, Shortages as the China Outbreak Plays Out, February 17, 2020, https://www.fiercepharma.com/manufacturing/fda-anticipates-drug-and-device-disruptions-as-china-outbreak-plays-out (accessed April 3, 2020). See Exhibit 434.

E. FDA Cites Shortage of One Drug, Exposing Supply-Line Worry

Introduction

"China is key supplier of chemical and raw materials and other pharmaceutical ingredients for medicines."

Coronavirus Outbreak Exposed in China:

- Factory shutdowns across China "exposed an uncomfortable health-care reality: Many medicines rely on raw materials that are made in that country"
- FDA contacted 180 drug manufacturers
- Requested them to provide notification of any expected supply shortages

- Makers of roughly 20 products the agency has identified as containing key pharmaceutical ingredients from China.

"China is a key supplier of the chemical and raw materials for popular blood pressure medicines and several older antibiotics that are no longer manufactured in the U.S., such as doxycycline and penicillin."

"The antibiotic supply chain is becoming increasingly fragile, even without a global epidemic centered in the major manufacturing location," said Dan Diekema, director of infectious diseases at the University of Iowa Healthcare, a hospital. "If we were to have major disruptions that caused shortages of several antibiotics at once, it would challenge our ability to adapt."

Other problems include:

- Some Chinese firms stopped shipping to manufacturers in India
- Indian generic-drug industry relies on China for much of its active ingredients
- "Pharma industry is pretty much bound hand and foot with manufacturers in China."
- "FDA says it has no way to track API volume out of China."
- Trying to "piece together" the Chinese supply chain includes examining numerous datasets in shipping records, company records, FDA data

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from the Wall Street Journal:

> "The intricacies of the supply chains for individual medicines—which companies keep under wraps for competitive reasons—remain hidden from the public. While the FDA requires manufacturers to report when there is a shortage of a specific product, companies that make the raw materials aren't subject to such demands. Nor must they disclose the size, or timing, of shipments being made to the U.S., limiting the ability of hospitals and other providers to plan for potential supply disruptions….
>
> "'We technically have no idea what is actually manufactured in China,' said Soumi Saha, senior director of advocacy at Premier, one of the largest group-purchasing organizations in the U.S. contracting for drugs and other supplies for hospitals. 'We're missing that upstream visibility.'"

Citation: Wall Street Journal, FDA Cites Shortage of One Drug, Exposing Supply-Line Worry, February 28, 2020, https://www.wsj.com/articles/coronavirus-slows-drug-production-in-china-the-worlds-pharmacy-11582900885 (accessed March 13, 2020). See Exhibit 435.

5. The World Health Organization and Vaccines Made in China

Introduction

"When WHO pre-qualified a Chinese-made vaccine for the first time last October [2013], the move showed what Chinese vaccine manufacturers could potentially achieve and—in a sense—paved the way for others to follow suit.

"'The prequalification of the Japanese encephalitis vaccine in China is a big step forward, and now several other Chinese producers are interested in obtaining prequalification for their vaccines,' says Melissa Malhame, whose team at the GAVI Secretariat in Geneva works with vaccine manufacturers around the world to ensure sufficient supply of high quality vaccines at affordable prices.

"This and other Chinese vaccines are licensed by the China Food and Drug Administration (CFDA) that is part of China's National Regulatory Authority (CNRA), which received WHO's seal of approval in March 2011, after finding that it met WHO standards for vaccine regulatory oversight.

"In July, this status was renewed, after a successful WHO reassessment of the vaccine regulatory part of the CNRA. WHO Director-General Dr. Margaret Chan welcomed the news saying: 'As a result of this evaluation, WHO is confident in the quality, safety and effectiveness of vaccines that are made in China.'"

The WHO's Global Vaccine push with China:

- The WHO's first prequalified Chinese manufacturer in 2013
- WHO expects more "Chinese vaccine manufacturers will follow suit"
- "Apply for prequalification later this year [2014.]"

WHO China Vaccine Highlights:

- China currently produces nearly all of the commonly-used vaccines for viral diseases such as
    1. Influenza
    2. Measles
    3. Rabies for humans
    4. Mumps

5. Rotavirus
6. Hepatitis A & B
7. Bacterial diseases, including typhoid, tetanus and diphtheria,

"Once a new vaccine is licensed, every lot is chemically and biologically tested before it is released along the supply chain—a lot-release system that has been in place since the mid-2000s."

However, China needs to "restore public confidence. These include improved information sharing and communication between authorities to identify problems or risks, adjust and upgrade standards and improve the quality of vaccines. The industry also needs to step up its post-marketing surveillance while more stringent regulation is needed."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the WHO prequalifies Chinese-made vaccines to promote the spread of vaccines throughout the world.'

Citation: World Health Organization (WHO), China Enters the Global Vaccine Market, WHO Bulletin 9-2014, https://www.who.int/bulletin/volumes/92/9/14-020914/en/ (accessed June 14, 2020). See Exhibit 436.

6. China Vaccine Supply Chain

A. China's Emerging Vaccine Industry

Introduction

> "The Chinese vaccine industry is developing rapidly due to an emerging and large market for current and new vaccines, a large potential for local vaccine manufacturing both in the public and private domain, and a governmental orientation towards national vaccine self-sufficiency. There are currently over 40 companies and institutions manufacturing a large variety of traditional (EPI) and some new vaccines."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published in Human Vaccines:

> "Multinational vaccine companies show an increasing interest in expanding their presence and are entering the Chinese market by taking majority shares in

Chinese companies. *GSK* announced in 2009 to take a 65% stake in a joint venture with the Chinese firm Walvax (No. 24 in Table 3) for the development, manufacture and supply to China's public vaccine market of MMR."

Citation: Human Vaccines, China's Emerging Vaccine Industry, July 2010, Vol. 6, Issue 7, https://pubmed.ncbi.nlm.nih.gov/20523120/ (accessed June 14, 2020). See Exhibit 437.

B. China Drug Exports to U.S. Rise, but Companies Struggle with Quality

Introduction

"Chinese companies now account for more than 50% of the global active pharmaceutical ingredient (API) market. It has more than 500 companies registered to sell in the U.S. and 10 times that many serving its own market. But many of those continue to struggle to meet international standards.

"As an example, *Bloomberg* points to the fact that last year, Chinese authorities ordered about 700 Chinese firms to review pending drug applications and withdraw any that were false or incomplete in an effort to step up its drug quality oversight. About three-quarters of the applications were voluntarily withdrawn or rejected by China's regulators, even though some of the drugs also were approved for sale in the U.S.

"Several of the company's explained the disparity to *Bloomberg* by saying that their products sold in China were tested by Chinese labs that provided faulty information while those sold in the U.S. were certified by research firms in North American companies and, as a result, are safe. It was a sentiment that echoed China's regulators."

Regulatory findings included:

- One company "lacking in some of the most basic GMP standards."
- Failed to write up or follow any processes for holding each lot for sampling
- Never received an approval from the quality control inspectors before release
- Failed to do stability testing to determine how the APIs should be stored
- Failed to establish APIs' "appropriate expiration dates"
- Failed to establish "procedures for regularly cleaning and maintaining equipment."

Other finds with two Chinese facilities:

- FDA warning letter noting dirty equipment
- Holes in the facility that allowed insects into clean rooms
- Chipped paint flaking off the ceiling above API equipment

1. Some had "products banned from entry into the U.S.

2. Another plant manipulated testing protocols

3. Turning in falsified batch test results on APIs.

"Despite the regulatory issues, Chinese companies continue to build business in the U.S. *Bloomberg* reports that China's drug exports to the U.S. grew 4% last year."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'Even while Chinese drug exports rise, Chinese drug manufacturers experience ongoing quality control problems'.

Citation: Fierce Pharma, China's Drug Exports to the U.S. Rise but Companies Struggle With Quality, August 30, 2016, https://www.fiercepharma.com/manufacturing/china-drug-exports-to-u-s-rise-but-companies-struggle-quality (accessed April 21, 2018). See Exhibit 438.

C. China's Expanding Role as a Vaccine Manufacturer

Introduction

"In March 2011, the World Health Organization (WHO) approved China's State Food and Drug Administration (SFDA) as a functional regulatory authority for vaccines. This approval means that the SFDA fulfills the WHO's criteria for international standards in vaccine regulation, and thus Chinese-made vaccines approved by the SFDA should ultimately meet internationally recognized standards and can apply for WHO prequalification status."

Chinese vaccine news updates in 2011:

- "July 2010 Merck and Sinopharm signed a cooperation agreement on HPV vaccine and several others" biologics
- China's vaccine industry possesses:
    1. Cutting-edge hardware
    2. Infrastructural elements in terms of buildings and machinery
- Software, however, is what Chinese companies were lacking:
    1. Management policies
    2. Management procedures
    3. Human resources and personnel
    4. Supply chain processes

5. Supply chain audit trails

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote, "'The concentration of players in China's vaccine industry is very low, so the competition is intense,' Yonglin Wu, vice president of China National Biotec Group."

Citation: The National Bureau of Asian Research, Preparing for the Global Market: China's Expanding Roles as a Vaccine Manufacturer, October 11, 2011, https://www.nbr.org/publication/preparing-for-the-global-market-chinas-expanding-role-as-a-vaccine-manufacturer/ (accessed June 14, 2020). See Exhibit.

D. China Investigates Vaccine Maker After Deaths of Infants

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the NY Times:

> "Health authorities in China are investigating one of the nation's biggest vaccine makers after eight infants died in the past two months following injections that were meant to immunize them against hepatitis B….
>
> "Six of the deaths have been linked to vaccines produced by Shenzhen Kangtai; the two other infant deaths occurred recently after the use of a hepatitis B vaccine produced by another drug maker, Beijing Tiantan Biological Products….
>
> "Merck gave the company the biological technology to produce a hepatitis B vaccine royalty free as part of an unusual joint venture aimed at improving health standards in China."

Citation: New York Times, China Investigates Vaccine Maker After Deaths of Infants, December 25, 2013, https://www.nytimes.com/2013/12/26/world/asia/china-investigates-vaccine-maker-after-infant-deaths.html (accessed March 18, 2017). See Exhibit 440.

E. Vaccine Scandal and Crisis in Public Confidence in China

Introduction

"In March, 2016, a vaccine scandal in Shandong province, eastern China, has led to the deaths of four children. According to state media, the prime culprit, a former pharmacist, was

caught delivering vaccines to medical facilities on bicycles without approved storage conditions. The Shandong Food and Drug Administration made public a list of 25 problematic vaccines."

The Chinese 'problematic vaccines' include:

- Polio
- Mumps
- Rabies
- Hepatitis B
- Encephalitis
- Meningococcal vaccines

These *problematic vaccines* were sold "illegally in at least 24 provincial areas since 2011. Those vaccines are worth more than ¥570 million (i.e., US$88 million)."

> "The vaccine scandal has caused public panic across China. Although relevant government departments have stressed that the improperly stored vaccines are unlikely to cause deaths directly, public confidence in the health department was still hard hit. There is no doubt that the vaccine management system has a serious vulnerability, which permitted the improperly stored vaccines to be distributed across two-thirds of the country in the past 5 years. The problem of the public health management system has already been recognized since 2008, when toxic chemical melamine was discovered to have been added to formula milk, causing at least six infants to die….
>
> "The Chinese Government should address the shattered public confidence made worse by the vaccine scandal. The health management system should be improved to ensure that vaccines are properly stored and transported, and transparency of supervision should also be enhanced."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote, "The vaccine scandal has caused public panic across China."

Citation: The Lancet, Vaccine Scandal and Crisis in Public Confidence in China, June 11, 2016, Vol. 387, Issue 10036, p2382, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30737-1/fulltext (accessed March 18, 2017). See Exhibit 441.

F. China Recalls Defective Vaccines Exported to Overseas Markets

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the *Insurance Journal*, "Investigators in China have begun recalling defective vaccines produced by a Chinese drugmaker from domestic and overseas markets, health authorities said."

Citation: Insurance Journal, China Recalls Defective Vaccines Recalled from Overseas Markets, August 9, 2018, https://www.insurancejournal.com/news/international/2018/08/09/497593.htm (accessed December 5, 2019). See Exhibit 442.

7. Foreign Vaccine Manufacturing

A. Merck Opens New Manufacturing Facility in Hangzhou, China

Introduction

In a Merck press release, 16 April 2013, the company highlights its longtime commitment to China and the Chinese market.

Highlights include:

- "It also extends our long-standing partnership with the Chinese government and our unequivocal commitment to help broaden access to quality healthcare throughout China."
- "Merck built its first China plant in 1994 in Hangzhou."
- "Merck also has an R&D Center in Beijing, three manufacturing facilities throughout the country, a marketing and sales organization headquartered in Shanghai, and employs more than 5000 employees in China."
- "Over the past two decades, Merck has successfully introduced more than 40 innovative medicines and vaccines in China."
- "The new facility in HEDA joins an integrated, interdependent network of 72 Merck facilities that supply medicines and vaccines to more than 140 countries."
- "The HEDA facility is one of the most advanced and largest packaging facilities in China and the region."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'Merck has a long-standing partnership with the Chinese government'.

Citation: Merck Press Release, Merck Opens New Manufacturing Facility in Hangzhou, China, April 16, 2013, https://www.mrknewsroom.com/press-release/corporate-news/merck-opens-new-manufacturing-facility-hangzhou-china/ (accessed March 18, 2017). See Exhibit 443.

B. Merck: Top-Selling Vaccine Made Cheap Shows Challenge

Introduction

In January 2015, *Bloomberg News* reported that cheaper, lower pricing has put pressure on Merck's vaccine dominance and business model.

"Serum Institute of India Ltd., which makes vaccines injected in 65 percent of the world's children, is targeting newer vaccines, including one for the human papillomavirus that could be available in late 2018 and sell at a third of the price of Merck & Co.'s blockbuster Gardasil.

This has impacted Merck and other large pharmaceuticals, because:

- Heavy investments needed to develop vaccines
- High failure rate of potential candidates.
- UNICEF procures their vaccines cheaply for the governments of the world's poorest countries,
- Merck earned $1.8 billion from sales of Gardasil in 2013
- Driven by approvals for use among boys
- Purchases for the U.S. Centers for Disease Control vaccine stockpiles

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'cheaper, lower pricing affects vaccine development'.

Citation: Bloomberg News, Top-Selling Vaccine Made Cheap Shows Challenge to Merck: Health, January 26, 2015, https://www.bloomberg.com/news/articles/2015-01-26/top-selling-vaccine-made-cheap-shows-challenge-to-merck-health (accessed March 14, 2017). See Exhibit 444.

C. Merck & Co Signs China Vaccines Alliance

Introduction

In July 2010: "Merck & Co. is pushing on with its emerging markets strategy and linking up with China's Sinopharm Group Co."

Highlights include:

- They signed "a statement of mutual intent"
- It will focus on cooperation of HPV vaccines
- They seek to move to a joint-venture on HPV vaccine manufacturing
- Sinopharm is the largest state-owned pharmaceutical group.
- Sinopharm is "China's largest bio-pharmaceutical manufacturing company
- Sinopharm is the biggest (and the world's third largest) drug distribution company in China.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'Merck engages in joint ventures with Chinese vaccine manufacturers'.

Citation: Pharma Times, Merck & Co. Signs China Vaccine Alliance, July 27, 2010, http://www.pharmatimes.com/news/merck_and_co_signs_china_vaccines_alliance_982699 (accessed June 15, 2020). See Exhibit 445.

8. Foreign Vaccine Supply Chain

A. Indian pharma threatened by COVID-19 shutdowns in China

Introduction

"As factories in China are closed, India is working to maintain supplies of active pharmaceutical ingredients (APIs)."

The issues with COVID19 global supply chain are:

- "Indian pharmaceutical companies procure almost 70% of the APIs for their medicines from China, the world's leading producer and exporter of APIs by volume."

- "India's dependence on China for APIs is increasingly seen as a matter of health security.
- "In 2018, the central government in India set up a taskforce to reviving the API sector."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Lancet: "Indian pharmaceutical companies procure almost 70% of the APIs for their medicines from China, the world's leading producer and exporter of APIs by volume."

Citation: The Lancet, Indian Pharma Threatened by COVID-19 Shutdowns in China, February 29, 2020, Vol. 395, Issue 10225, p675, https://www.thelancet.com/journals/langlo/article/PIIS0140-6736(20)30459-1/fulltext (accessed March 4, 2020). See Exhibit 446.

B. Almost 40 Indonesian medical facilities procured fake vaccines

Introduction

Securing Industry journal: "Ongoing investigations into the scale of the fake vaccine racket in Indonesia have uncovered counterfeits in 37 medical facilities across nine provinces.

Now Indonesia's Food and Drug Monitoring Agency (BPOM) says it has discovered fake vaccines procured by 37 medical facilities across nine provinces:

- South Sumatra
- Lampung
- Banten
- Jakarta
- West Java
- East Java
- Bangka Belitung
- Riau
- Riau Islands.

The investigation resulted in finding:

- 39 fake vaccines in all," said Arustiono, director for drugs distribution at BPOM
- "A tip off from a major pharma company that some of its products had been counterfeited."
- "Brands produced by GlaxoSmithKline, Sanofi and Bio Farma are believed to have been subject to fake copies."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the international vaccine industry is afflicted by a fake vaccine racket'.

Citation: Securing Industry, Almost 40 Indonesian Medical Facilities Procured Fake Vaccines, July 12, 2016, https://www.securingindustry.com/pharmaceuticals/almost-40-indonesian-medical-facilities-have-fake-vaccines/s40/a2857/#.Xud8wpbQi-u (accessed March 12, 2020). See Exhibit 447.

C. 2016 Product Security Report

Introduction

The Pharmaceutical Commerce "2016 Product Security Report" leads in with the follow issue:

"… counterfeiting, diversion and stolen pharmaceutical cargo are not global problems: the situation in Africa and other parts of the underdeveloped world is still dire, and counterfeiters and diverters still knock on the doors of national pharmaceutical supply chains around the world."

The Report discussed the new, at the time of publication, "Major scandal in China, involving millions of doses of childhood vaccines that were improperly stored (and therefore inactivated) by a small group of traders who then sold the drugs to local pharmacies across the country."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Product Security Report, "…counterfeiting, diversion and stolen pharmaceutical cargo are not global problems: the situation

in Africa and other parts of the underdeveloped world is still dire, and counterfeiters and diverters still knock on the doors of national pharmaceutical supply chains around the world."

Citation: Pharmaceutical Commerce, 2016 Product Security Report, June 8, 2016, https://pharmaceuticalcommerce.com/special-report/2016-product-security-report/ (accessed March 11, 2020). See Exhibit 448.

D. As India, China Drug Industries Mature, FDA Scrutiny an Overhang

Introduction

In the industry journal Biopharma Dive 2018, it discusses the myriad issues with foreign suppliers of drugs and vaccines in foreign countries not able to meet many of the FDA standards and regulations on quality control and quality assurance guidelines.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Biopharma Dive, "Dozens of other India- and China-based drug manufacturers flagged by the FDA for not keeping their operations up to code."

Citation: Biopharma Dive, As India, China Drug Industries Mature, FDA Scrutiny an Overhang, April 23, 2018, https://www.biopharmadive.com/news/as-india-china-drug-industries-mature-fda-scrutiny-an-overhang/521719/ (accessed March 23, 2020). See Exhibit 449.

E. FDA halt of foreign inspections may delay some new product approvals

Introduction

In the industry journal *Fierce Pharma*, the author highlighted the issues of how widespread the COVID19 outbreak has impacted the FDA and its overseas inspection operations.

"The FDA has decided that the risk of inspectors crossing paths with COVID-19 is greater than the risk to consumers of drugmakers failing to meet FDA standards and putting poor quality drugs on the market. The agency has decided to halt inspections of all foreign drug manufacturers after earlier putting inspections in China on hold."

As a result of the global pandemic, the FDA will:

- Consider "mission critical" inspections on a case-by-case basis

- Postpone foreign inspections in April.
- Rely on help from regulators in other countries
- Testing products at the border for safety and
- Wield authority to deny entry to drugs considered defective or unsafe.

"Already this year, the agency has banned drugs from manufacturers in Bulgaria, China, Denmark, Germany, India, Mexico and Venezuela. Just this week it banned drugs and products from a Chinese company called Hangzhou Linkeweier Daily Chemicals Co. that included faulty antibacterial wipes. But bans generally stem from plant inspections."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'as a result of the Covid-19 pandemic, FDA is not completing ordinary inspections of foreign vaccine manufacturers'.

Citation: Fierce Pharma, FDA Halt of Foreign Inspections May Delay Some New Product Approvals, May 11, 2020, https://www.fiercepharma.com/manufacturing/fda-halt-foreign-inspections-may-delay-some-new-product-approvals (accessed March 23, 2020). See Exhibit 450.

F. "Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices"

Introduction

The 2016 U.S. Government Accountability Office (GAO) Report evaluated the FDA's foreign drug inspection program in its 63-page report.

In summary, the GAO Report noted, "Increased its foreign drug inspections and enhanced its ability to prioritize drug establishments for inspection. The number of foreign inspections has consistently increased each year since fiscal year 2009. Beginning in fiscal year 2015, FDA conducted more foreign than domestic inspections."

The FDA improved the following inspection areas:

- Accuracy and completeness of information on its catalog of drug establishments subject to inspection.

- "Reduced its catalog of drug establishments with no inspection history to 33 percent of foreign establishments, compared to 64 percent in 2010."
- "However, the number of such establishments remains large, at almost 1,000 of the approximately 3,000 foreign establishments."
- "FDA plans to inspect all of these establishments over the next 3 years."
- Made progress in its "strategic planning for its offices in China, Europe, India, and Latin America."
- "But the lack of an assessment is inconsistent with federal standards for internal controls."

The FDA uses "two (2) performance measures to assess the foreign offices—number of medical product inspections and number of collaborative actions—the collaborative action measure does not capture the offices' unique contributions to drug safety."

Other findings include:

[Page 9]: "Our work focused on human drugs regulated by CDER and not on most biologics, medical devices, veterinary medicines, or other items or products for which FDA conducts inspections. Further, our work focused on activities related specifically to the foreign drug inspection program. As part of its oversight of imported drugs, FDA undertakes other activities, such as working toward international harmonization of regulatory requirements, which are beyond the scope of our review."

[Pages 13-14]: "FDA uses multiple databases to select foreign and domestic establishments for surveillance inspections, including":

- "The electronic Drug Registration and Listing System (eDRLS) contains information on foreign and domestic drug establishments that have registered with FDA to market their drugs in the United States. Establishments are required to register annually with FDA. Information in eDRLS includes the company's name, address, and the drugs they manufacture for commercial distribution in the United States, as reported by the establishment.

- "FACTS contains information on domestic and foreign establishments inspected by ORA, the type of inspection conducted, and the outcome of those inspections. Investigators and laboratory analysts enter information into FACTS following completion of an inspection."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from the GAO report:

> **[Page 37]:** "FDA Continues to Experience High Vacancy Rates in Its Foreign Offices, Limiting Its Ability to Ensure Drug Safety. As of July 2016, the foreign offices were authorized to have 54 full-time positions overseas, but 25 of these positions (46 percent) were vacant."
>
> **[Page 45]:** "The rapid pace of globalization has complicated the agency's efforts to ensure the safety of our drug supply. Our concerns with FDA's response to globalization go back two decades. In that time, we have made multiple recommendations to help the agency tackle this challenge. The enactment of FDASIA also provided the agency with new flexibility to help FDA cope with the growth of drug manufacturing overseas."

Citation: The U.S. Government Accountability Office (GAO) Report, Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices, December 2016, https://www.gao.gov/assets/690/681689.pdf (accessed June 15, 2020). See Exhibit 451.

G. Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program

Introduction

The December 10, 2019, testimony of Janet Woodcock, M.D., Director - Center for Drug Evaluation and Research before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.

The Globalization of Pharmaceutical Manufacturing:

"This shift is reflected in the CDER's Site Catalog ("Catalog"), which lists all drug manufacturing facilities worldwide that are subject to routine FDA inspections. [3] As of August 2019, 28 percent of facilities manufacturing APIs and 47 percent of the facilities producing finished dosage forms (FDFs) of human drugs for the U.S. market were located in the United States."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the attached Pie Chart breakdown by region of APIs manufacturing facilities:

- 13% - China
- 26% - European Union
- 28% - United States
- 18% - India
- 13% - Rest of the World
- 02% - Canada

First Citation: U.S. Food & Drug Administration, Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program, December 10, 2019, https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019 (accessed March 31, 2020). See Exhibit 452.

Second Citation: House Committee on Energy & Commerce, Subcommittee Oversight & Investigations, "Hearing on Securing the U.S. Supply Chain: Oversight of FDA's Foreign Inspection Program", December 10, 2019, https://energycommerce.house.gov/subcommittees/oversight-and-investigations-116th-congress (accessed June 15, 2020). See Exhibit 453.

H. Outsourcing in the Digital Age

Introduction

On February 19, 2020, the industry website Pharma Manufacturing published an article of critical elements that continue to impede and be a friction point on the seamless and efficient inspections and information on overseas drug and biologics manufacturing.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Pharma Manufacturing:

> "Upwards of 60 percent of pharma manufacturing is outsourced. And while the industry has shifted dramatically in that respect, it has not changed in other areas.

> Pharma— including drug companies, generics makers and contract manufacturing organizations (CMOs)—lags far behind other industries in the use of modern control and information technologies to improve quality and efficiency."

Citation: Pharma Manufacturing, Outsourcing in the Digital Age, February 19, 2020, https://www.pharmamanufacturing.com/articles/2020/outsourcing-in-the-digital-age/ (accessed March 11, 2020). See Exhibit 454.

I. Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India

Introduction

May 2019, *NBC News* interviewed by an ex-FDA inspector and the FDA media representative(s) about ensuring quality control at several Indian pharmaceutical manufacturing plants. Former FDA inspector, "Massoud Motamed says the FDA struggles to police the sprawling number of overseas drug manufacturers who may hide problems in their production lines."

> "The valsartan case underscores a new reality in the pharmaceutical industry—a growing reliance on foreign manufacturers to provide the raw ingredients for drugs sold in the U.S. According to FDA data, roughly 85 percent of the facilities manufacturing the ingredients in American drugs are located overseas, many from China and India where production costs are low and experts say local government oversight is less stringent."

Issues on safety of medicines and biologics consumed in the U.S.

- The ex-FDA inspector said: "More systemic issue has largely gone unreported."
- FDA inspectors "struggle to keep up with foreign drug manufacturers that may bury or hide problems in their production."
- In 2018, the "FDA inspected only one in five registered human drug manufacturing facilities abroad, according to agency data."
- U.S. inspectors "scrambled to review a sprawling network of overseas drug production plants."
- The FDA is "left to rely on the word of the facility managers."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote:

"Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise," reads a January 2019 FDA press release.

Citation: NBC News, Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India, May 10, 2019, https://www.nbcnews.com/health/health-news/tainted-drugs-ex-fda-inspector-warns-dangers-u-s-meds-n1002971 (accessed March 23, 2020). See Exhibit 455.

J. Global Vaccine Market Features and Trends

Introduction

In 2018, Miloud Kaddar, Sr. Adviser and Health Economist at the World Health Organization (WHO), presented "Global Vaccine Market and Trends" at the Immunization, Vaccines and Biologics (IVB) at the WHO in Geneva.

Covering a broad range of topics, Mr. Kadder presented the following key highlights on the then current state of the global vaccine market.

[Page 7]: Main Features of Global Vaccine Market

- The market "tripled in value from USD 5B in 2000 to almost USD 24B in 2013
  - Influenza vaccine market: estimated at $2.9 billion in 2011 to $3.8 billion by 2018
  - US : $1.6 billion in 2011 to $2.2 billion in 2018
- Global market projected to rise to USD 100 B by 2025
- More than 120 new products in the development pipeline
- 60 are of importance for developing countries

[Page 14]: Growth Factors

- Importance of communicable diseases and new threats
- Cost effectiveness of immunizations
- New funding opportunities (Gov, PPP, donors, Foundations)
- New research techniques and manufacturing technologies
- Increasing demand, new target population, larger emerging markets

- Higher prices, improved profitability for the industry (blockbuster vaccines.

[Page 21]: New Business Multinational Corporation Model Is Emerging?

- More mapping, market segmentation and price differentiation
- Outsourcing selected part of R&D, production and commercialization
- Access to promising markets and local capacities, low costs
- Risk sharing with countries and funders
- Collaborative networks and active presence at GHIs

[Page 38]: Concerns

There were several areas of concern noted by Mr. Kadder, the top three (3) include:

- Oligopoly, limited supply for DC and Shortage risks
- Upstream factors:
  - Technology transfer and IPRs,
  - R&D for most needed vaccines,
  - DCVM R&D capacity
- New vaccine costs and prices

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the international vaccine market is growing exponentially'.

Citation: Presentation by World Health Organization's Senior Adviser, Health Economist Miloud Kadder, "Global Vaccine Market Features and Trends", 2010. https://www.who.int/influenza_vaccines_plan/resources/session_10_kaddar.pdf (accessed June 15, 2020). See Exhibit 456.

9. Globalists Planning Pandemic Response Financing Creates A National Security Issue for the United States

A. Global Preparedness Monitoring Board (GPMB) Meeting

Introduction

On April 1-2, 2019, the World Health Organizations new unit, the Global Preparedness Monitoring Board (GPMB) held a meeting to assess the then current issues with global pandemic preparedness, risks, and gaps.

The Board highlighted five (5) critical issues, including these three below:

- "The lack of community trust and acceptance has emerged as a critical bottleneck for effective preparedness and response;
- "The lack of progress in mobilizing domestic and international financing to prepare and respond to emergencies, and to finance implementation of NAPHS and preparedness in low- and middle-income countries;
- "The lack of standardized definitions of preparedness (including their use to monitor financing/expenditures)."

Among the six (6) "actions and priorities" the Board identified their attention, Point No. 2 stands out, reading: "Global preparation for a fast-moving, high impact airborne pathogen outbreak such as for influenza, or an accidental or deliberate release."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in the months before Covid-19 traveled to the United States the GPMB engaged in strategic planning for a fast-moving, high impact airborne pathogen outbreak such as for influenza, or an accidental or deliberate release.'

Citation: The WHO's Global Preparedness Monitoring Board, Summary: GPMB Board Meeting, April 1-2, 2019, IFRC, Geneva, Switzerland, https://apps.who.int/gpmb/assets/pdf/GPMB_Board_Meeting_1-2_April_2019_Summary.pdf (accessed June 15, 2020). See Exhibit 457.

B. GPMB first annual report, "A World at Risk"

Introduction

On September 22, 2019, the GPMB published, "A World at Risk: Annual Report on Global Preparedness for Health Emergencies." The report focused on "Seven (7) urgent actions to prepare the world for health emergencies."

They included:

1. Heads of government must commit and invest
2. Countries and regional organizations must lead by example
3. All countries must build strong systems
4. Countries, donors and multilateral institutions must be prepared for the worst
5. Financing institutions must link preparedness with financial risk planning
6. Development assistance funders must create incentives and increase funding for preparedness
7. The United Nations must strengthen coordination mechanisms

Under No. 7, Progress indicator(s) by September 2020, Point No. 2 reads:

"The United Nations (including WHO) conducts at least two systemwide training and simulation exercises, including one for covering the deliberate release of a lethal respiratory pathogen." (Pages 10 & 39 of 48).

Under section, **All economies are vulnerable**, the report findings note (pg. 15): "Epidemics and pandemics disrupt trade and tourism, both of which are major global economic drivers and have provided a huge boost to African economies in recent years."

In 2017:

- "Global merchandise trade estimated at US$ 17.43 trillion;
- "Commercial services, including tourism: US$ 5.19 trillion:
- "Combined, they made up about 18% of the global economy."

The section concludes, "The chances of a global pandemic are growing" and "Trust in institutions is eroding."

In main section No. 5, **Financing institutions must link preparedness with economic risk planning**, (pg. 28) it opens with the following statement:

> "To mitigate the severe economic impacts of a national, regional epidemic and/or a global pandemic, the IMF and the World Bank must urgently renew their efforts to integrate preparedness into economic risk and institutional assessments, such as the IMF's next cycle of Article IV consultations with countries, and the World Bank's next Systematic Country Diagnostics for IDA credits and grants. The

> funding replenishments of the IDA, Global Fund to Fight AIDS, TB, and Malaria, the and Gavi Alliance should include explicit commitments regarding preparedness."
>
> Finally, the GPMB defines itself (pg. 4):
>
> "As an independent monitoring and advocacy body, the Global Preparedness Monitoring Board (hereafter referred to as the Board or GPMB) urges political action to prepare for and mitigate the effects of global health emergencies. Co-convened in May 2018 by the World Bank Group and the World Health Organization, the Board builds on the work of the Global Health Crises Task Force and Panel, created by the United Nations Secretary-General in the wake of the 2014- 2016 Ebola epidemic."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the GPMB planned for the United Nations by September 2020 to conduct at least two systemwide training and simulation exercises, including one for covering the deliberate release of a lethal respiratory pathogen'.

Citation: The WHO's Global Preparedness Monitoring Board, A World at Risk Report, September 22, 2019, https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf (accessed June 15, 2020). See Exhibit 458.

C. The World Bank Statement on the GPMB

Introduction

On September 10, 2018, the World Bank released a statement about the GPMB and its quest to research, develop, and publish its first annual report by the following September. That was agreed to by all United Nations (UN) parties involved, include the WHO, the World Bank, the UN, and the GPMB at the meeting held at the UN headquarters in Geneva, Switzerland. "Despite all the progress we have made, the world remains vulnerable," said Dr. Tedros Adhanom Ghebreyesus, WHO Director-General. "The Global Preparedness Monitoring Board brings together deep experience and expertise to help keep the world safe."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the GPMB is officially recognized and supported by the WHO and World Bank'.

Citation: World Bank press release, Global Preparedness Monitoring Board Convenes for the First Time in Geneva, September 10, 2018, https://www.worldbank.org/en/news/press-release/2018/09/10/global-preparedness-monitoring-board-convenes-for-the-first-time-in-geneva (accessed May 13, 2020). See Exhibit 459.

D. The GPMB's Board of Directors

Introduction

Since it's finding as a new unit of the World Health Organization (WHO) in May 2018, the Global Preparedness Monitoring Board created a top-down structure with twin co-chairs, with thirteen (13) additional board members.

They include the following notable members and their potential for conflicts of interest related to healthcare policies and implementation in the United States.

They include:

- **Dr. Anthony S Fauci**
  Director, National Institute of Allergy and Infectious Diseases, USA
- **Dr. George F. Gao**
  Director-General, Chinese Center for Disease Control and Prevention, People's Republic of China
- **Dr. Victor Dzau**
  President, The National Academy of Medicine, USA
- **Dr. Chris Elias**
  President, Global Development Program, Bill & Melinda Gates Foundation, USA
- **Sir Jeremy Farrar**
  Director, Wellcome Trust, UK
- **Henrietta Fore**
  Executive Director, UNICEF

At the global pandemic preparedness board has said the US director of the National Institute of Allergy and Infectious Diseases (NIAID), a division of the US National Institute of Health (NIH), and the director-general of the Chinese CDC. Then there is the executive of the ubiquitous, non-profit Bill and Melinda Gates Foundation, and the director of Wellcome Trust, another charitable health foundation based in the United Kingdom. Wellcome Trust has an investment portfolio worth $33 million USD (26.8 million British pounds).

The investment strategy reads, in part: "An in-house team of investment professionals manage Wellcome's portfolio. Their aim is to maximize returns over the long term to ensure that Wellcome continues to have sustainable resources for our charitable activities."

At the Bill & Melinda Gates Foundation, a similar two-tier structure exists to "maximize" return on investment and make charitable grants and funding, related to global healthcare. On the Gates Foundation website page, *Who We Are, General Information, Financials and the Foundation Trust*, the section, "How the Foundation Trust works," it reads:

"The Foundation Trust holds the endowment, including the annual installments of Warren Buffet's gift, and funds the foundation. Bill and Melinda [Gates] are the trustees for the Foundation Trust, and the endowment continues to be managed, as it has been for more than 10 years, by a team of outside investment managers."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in this offshore entity GPMB, Drs. Fauci and Dzau convene to make policy, recommendations, share potential intelligence and intellectual property with not only the Chinese CDC, but also unelected officials at global health foundations.'

Citation: The WHO's Global Preparedness Monitoring Board, 2018-2020, https://apps.who.int/gpmb/board.html (accessed May 26, 2020). See Exhibit 460.

E. The Event 201 Simulation Exercise

Introduction

The Event 201 simulation of a coronavirus pandemic, which led to killing 65 million *virtual* people in a computer model, was held on October 18, 2019. The three main partners behind the

wargames training exercise included the Bill and Melinda Gates Foundation, John Hopkins University (JHU), and the World Economic Forum.

In a preprint paper (October 2019), "The Event 201" simulation exercise, written by author Domina Petric at the University Hospital Centre in Split, Croatia, stated, in part:

> "… The exercise illustrated areas where public/private partnerships will be necessary during the response to a severe pandemic in order to diminish large-scale economic and societal consequences. Event 201 simulated an outbreak of a novel zoonotic coronavirus transmitted from bats to pigs to people that eventually becomes efficiently transmissible from person to person, leading to a severe pandemic."

Key parameters of the study and its findings:

- The pathogen was modeled on SARS, but it is…
- More transmissible in the community setting by people with mild symptoms;
- No possibility of a vaccine being available in the first year;
- A "fictional antiviral drug" helps the sick, but does not…
- "Significantly limit spread of the disease";
- The pandemic's "number of cases increases exponentially, doubling every week."

Following the seven recommendations made by the Event 201 panel of experts (pg. 3), it reads:

> "Among the selected 'players' as they were called, was the **professor George Fu Gao** [the author's emphasis], who is director of the Chinese Center for Disease Control and Prevention since 2017. His specialization includes research on influenza virus interspecies transmission (host jump). He is also interested in virus ecology, especially the relationship between influenza virus and migratory birds or live poultry markets and the bat-derived virus ecology and molecular biology."

Other *players* for the pandemic exercise, included Rear Admiral Stephen C. Redd, director of the Office of Public Health Preparedness and Response at the U.S. CDC, as well as executives from pharmaceutical corporations Johnson & Johnson, Inovio, the "Gates-backed" Coalition for Epidemic Preparedness Innovations (CEPI), and Lufthansa Group Airlines.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in the months before Covid-19 traveled to the United States, the participants in The Event 201 engaged in strategic planning for a coronavirus pandemic.'

Citation: Research Gate, The Event 201, Domina Petric at the University Hospital Centre in Split, Croatia, https://www.researchgate.net/publication/340236453_The_Event_201 (accessed June 15, 2020). See Exhibit 461.

F. Event 201 Model

Introduction

On October 11, 2019, Caitlin Rivers prepared The Event 201 Model document that captured the gamified simulation exercise.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Event 201 Model document:

"The Event 201 model simulates an outbreak of a moderately transmissible pathogen in a fully susceptible population. The model is intended to be a realistic representation of how a novel infectious disease could become a pandemic in the absence of adequate control measures."

Citation: John Hopkins University's Center for Security Health press release, The Event 201 Model, October 11, 2019, https://www.centerforhealthsecurity.org/event201/event201-resources/event201-model-desc.pdf (accessed June 15, 2020). See Exhibit 462.

G. Event 201: "Communication in a Pandemic"

Introduction

Marc Trotochaud and Divya Hosangadi prepared the "Communications in a Pandemic" document, which focused on the consortium's narrative, including the WHO and GPMB, of their information being "true" and authoritative. Realizing how social media allowed for dissenting voices, researchers, and journalists, who don't agree with the WHO's "true information" the Event 201 Team made sure to cover the trust gap between the global health agencies and those who oppose it.

The authors wrote: "True information about public health concerns is increasingly competing with false messages that can damage public confidence in health interventions and health authorities. These false messages are often defined as misinformation, erroneous information shared through various channels, and disinformation, purposefully spread false or misleading information."

The Communication noted several findings:

- Disinformation campaigns occur in the political world.
- They have been identified in the public health sector.
- In 2018, researchers "identified a concerted effort to spread disinformation and discord about vaccine safety."
- Disinformation impacts "time-dependent nature of outbreak response."
- "The corrosive effect misinformation can have on public trust."
- 50 countries made different government-led actions to combat misinformation.
- Actions include media literacy campaigns.
- Fact-checking websites.
- "Jailing users for publishing content deemed to be misinformation."
- Some "authorities shutdown social media sites or the internet entirely."

The authors identified one qualifier, writing: "However, censoring social media content and denying a population access to the internet has serious consequences."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'Event 201 participants endeavored to predetermine that Event 201's benefactors would be reliable for spreading truthful information during a pandemic.'

Citation: John Hopkins University's Center for Security Health, Event 201: Communication in a Pandemic, October 14, 2019, https://www.centerforhealthsecurity.org/event201/event201-resources/comms-fact-sheet-191014.pdf (accessed June 15, 2020). See Exhibit 463.

H. The Event 201 Scenario

Introduction

The Event 201 Scenario section, wrote: "Event 201 simulates an outbreak of a novel zoonotic coronavirus transmitted from bats to pigs to people that eventually becomes efficiently transmissible from person to person, leading to a severe pandemic."

Key findings from the Scenario, which were discussed in a mock, wargame session at the United Nations in New York City, on November 6, 2019, included:

- The disease starts in pig farms in Brazil.
- It spread "quietly and slowly."
- Then spread more "rapidly in healthcare settings."
- Investigators identify a South American pig farm as the epicenter of the outbreak.
- The epidemic explodes from South America.
- Air travel spread CAPS to "Portugal, the United States, and China."
- "The scenario ends at the 18-month point, with 65 million deaths."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Scenario section of the document, "The pandemic will continue at some rate until there is an effective vaccine or until 80-90 % of the global population has been exposed. From that point on, it is likely to be an endemic childhood disease."

Citation: John Hopkins University's Center for Security Health, The Event 201 Scenario, October 2019, https://www.centerforhealthsecurity.org/event201/scenario.html (accessed May 25, 2020). See Exhibit 464.

I. Report: Strengthening America's Health Security

Introduction

In November 2019, the Centers for Strategic and International Studies (CSIS), commissioned a report, "Ending the Cycle of Crisis and Complacency in U.S. Global Health Security." One project co-chair included Dr. Julie Gerberding, former director of the CDC (2002-2009), and currently Merck's executive vice president and chief patient officer.

Of the seven (7) themes the report discusses, including "restoring health security leadership" in the White House and raising billions of dollars for vaccines research and development, No. 7 highlights confronting "two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis."

The findings for the technology challenges include (pg. 12):

- Race to develop new vaccines against the mounting risks of "growing resistance" toward vaccines;
- The need to plan strategically against the known "resistance";
- Develop "new technologies for epidemic preparedness and response";
- The need for the "U.S. government should invest directly in the Coalition for Epidemic Preparedness Innovations (CEPI)";
- Heightened focus to develop a universal flu vaccine.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote on page 21 of the report, regarding supporting foreign, non-elected entities such as CEPI and the GPMB, stated by the Bill and Melinda Gates Foundation executive Trevor Mundel:

"Today we are facing the threat of a pandemic that could kill up to 80 million people and wipe out five (5%) percent of the global economy. The Global Preparedness Monitoring Board is doing critical work in partnership with the World Health Organization and the World Bank to ensure that more countries are prepared for global health crises."

Citation: The Centers for Strategic and International Studies (CSIS), November 2019, https://healthsecurity.csis.org/final-report/ (accessed June 15, 2020). See Exhibit 465.

J. COVID19 Statement 1 by Global Preparedness Monitoring Board

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'on January 27, 2020, the Global Preparedness Monitoring Board, related to COVID19 outbreak, statement called on: (2) "All countries and local

governments, including those that have not yet been affected, must urgently dedicate resources to building their essential preparedness capacities."

Citation: The WHO's Global Preparedness Monitoring Board, Statement on the Outbreak of 2019 novel-Coronavirus (2019-nCoV), January 27, 2020, https://apps.who.int/gpmb/assets/news/GPMB%20Statement%20on%202019%20nCoV.pdf (accessed June 15, 2020). See Exhibit 466.

K. COVID19 – Additional Statements by Global Preparedness Monitoring Board

Introduction

On January 30, 2020, the Global Preparedness Monitoring Board, related to COVID19 outbreak, statement detailed six (6) necessary steps to combat the pandemic, after commending the WHO and China for its "transparency" and "sharing of information" related to the virus genome sequence Chinese scientists published.

They include:

- All governments to "follow the WHO's technical guidance for control measures";
- Accelerate the coordinated development of vaccines;
- Use the Coalition for Epidemic Preparedness Innovations (CEPI) vaccine research CEPI is supporting;
- "Prompt and unrestricted sharing of coronavirus specimens and clinical samples essential to advancing research and development";
- "Countries must support and enable the WHO's central role in the response," including:
  - Sustainable financing the WHO's preparedness and response activities
  - Through "voluntary contributions"
  - Replenish the WHO's Contingency Fund for Emergencies
  - "Strengthen the WHO's communication capacity"
- All donors "support lower resource countries"

The final point reads, in part:

"Countries, institutions, the media and WHO should regularly and proactively communicate factual information about the outbreak, how to prepare for and prevent infection, in a transparent, timely, accurate and open manner…"

On March 3, 2020, the Global Preparedness Monitoring Board issued a statement that called for "key need" to be fulfilled:

"Fully funding the WHO to coordinate and prioritize support efforts to the most vulnerable countries." Also, "the Global Preparedness Monitoring Board (GPMB) is calling for the immediate injection of at least $8 billion [USD} of new funding."

The statement also noted issues with vaccine and therapeutic supply chains in China, due to the outbreak. China as the world's main supplier of pharmaceutical ingredients for many medicines—a significant disruption to production could substantially impact supplies…"

On April 1, 2020, the Global Preparedness Monitoring Board issued a statement that called on:

"G20 leaders should ensure that global public goods, such as R&D for vaccines, therapeutics and diagnostics for COVID-19, are funded and that mechanisms are put in place to ensure equitable and affordable access by all."

"As the Board highlighted in its 2019 annual report, *A World at Risk*, significant gaps persist that urgently need to be addressed to stop the COVID-19 crisis and mitigate its impact, but also to prevent future epidemics and pandemics. The GPMB stands ready to support WHO in assessing and monitoring these gaps."

On April 24, 2020, the Global Preparedness Monitoring Board statement called for:

"The GPMB highlighted this critical need and called for the immediate injection of at least USD 8 billion of new funding to support the development and production of new vaccines, drugs and diagnostics, and strengthen the global response to COVID-19."

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the GPMB is utilizing the Covid-19 pandemic to implement

its plans to increase the power and financial resources of the UN, China, the GPMB, and the GPMB's benefactors'.

First Citation: The Newsteader, Statement from the Global Preparedness Monitoring Board on the Outbreak of 2019-novel Coronavirus (2019-nCoV), January 30, 2020, https://thenewsteader.com/2020/01/30/statement-from-the-global-preparedness-monitoring-board-on-the-outbreak-of-2019-novel-coronavirus-2019-ncov/ (accessed June 15, 2020). See Exhibit 467.

Second Citation: The WHO's Global Preparedness Monitoring Board, Statement Calls for a Scaled-Up Global Response to COVID-19: Estimated Costs and Funding Sources, March 10, 2020, https://apps.who.int/gpmb/assets/pdf/GPMB_6March2020statement.pdf (accessed June 15, 2020). See Exhibit 468.

Third Citation: The WHO's Global Preparedness Monitoring Board, Statement on the COVID-19 Pandemic and the Extraordinary G20 Leaders' Summit on COVID-19, April 1, 2020, https://apps.who.int/gpmb/assets/pdf/Statement%20on%20the%20COVID-19%20pandemic%20and%20the%20Extraordinary%20G20%20Leaders'%20Summit%201Apr2020.pdf (accessed June 15, 2020). See Exhibit 469.

Fourth Citation: The WHO's Global Preparedness Monitoring Board, Statement on the launch of the Access to COVID-19 Tools (ACT) Accelerator, April 24, 2020, https://apps.who.int/gpmb/assets/pdf/GPMB_Statement_Accelerator_24_April.pdf (accessed June 15, 2020). See Exhibit 470.

CONCLUSION

Petitioners hereby request judicial notice of the foregoing facts.

ATTORNEYS FOR PETITIONERS

Date: 12-6-20

Gregory J. Glaser (SBN 226706)
4399 Buckboard Drive, Box 423
Copperopolis, CA 95228
Ph: (925) 642-6651
Fx. (209) 729-4557
greg@gregglaser.com

Date: 12.6.20

Ray L. Flores II (SBN 233643)
11622 El Camino Real Suite 100
San Diego, CA 92130
Ph. (858) 367-0397
Fx. (888) 336-4037
rayfloreslaw@gmail.com