

United States Department of State

Washington, D.C. 20520

April 24, 2023

Case No. FL-2021-00033

Gary Ruskin 4096 Piedmont Ave. #963 Oakland, CA 94611

Dear Mr. Ruskin:

As we noted in our letter dated March 24, 2023, we are processing your request for material under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. The Department of State ("Department") has identified an additional two responsive records subject to the FOIA. We have determined that both records may be released in part.

An enclosure explains the FOIA exemptions and other grounds for withholding material. Where we have made redactions, the applicable FOIA exemptions are marked on each record. Where applicable, the Department has considered the foreseeable harm standard when reviewing these records and applying FOIA exemptions. A list of the document identification numbers for the records withheld in full is attached to this letter. All non-exempt material that is reasonably segregable from the exempt material has been released and is enclosed.

We will keep you informed as your case progresses. If you have any questions, your attorney may contact Christopher M. Lynch, Trial Attorney, at Christopher.M.Lynch@usdoj.gov or (202) 353-4537. Please refer to the case number, FL-2021-00033, and the civil action number, 20-cv-08415, in all correspondence about this case.

Sincerely,

Diamonece Hickson

Chief, Litigation and Appeals Branch

Office of Information Programs and Services

Enclosures: As stated.

The Freedom of Information Act (5 USC 552)

FOIA Exemptions

- (b)(1) Information specifically authorized by an executive order to be kept secret in the interest of national defense or foreign policy. Executive Order 13526 includes the following classification categories:
 - 1.4(a) Military plans, systems, or operations
 - 1.4(b) Foreign government information
 - 1.4(c) Intelligence activities, sources or methods, or cryptology
 - 1.4(d) Foreign relations or foreign activities of the US, including confidential sources
 - 1.4(e) Scientific, technological, or economic matters relating to national security, including defense against transnational terrorism
 - 1.4(f) U.S. Government programs for safeguarding nuclear materials or facilities
 - 1.4(g) Vulnerabilities or capabilities of systems, installations, infrastructures, projects, plans, or protection services relating to US national security, including defense against transnational terrorism
 - 1.4(h) Weapons of mass destruction
- (b)(2) Related solely to the internal personnel rules and practices of an agency
- (b)(3) Specifically exempted from disclosure by statute (other than 5 USC 552), for example:

ARMSEXP Arms Export Control Act, 50a USC 2411(c)
CIA PERS/ORG Central Intelligence Agency Act of 1949, 50 USC 403(g)
EXPORT CONTROL Export Administration Act of 1979, 50 USC App. Sec. 2411(c)
FS ACT Foreign Service Act of 1980, 22 USC 4004
INA Immigration and Nationality Act, 8 USC 1202(f), Sec. 222(f)
IRAN Iran Claims Settlement Act, Public Law 99-99, Sec. 505

- (b)(4) Trade secrets and confidential commercial or financial information
- (b)(5) Interagency or intra-agency communications forming part of the deliberative process, attorney-client privilege, or attorney work product
- (b)(6) Personal privacy information
- (b)(7) Law enforcement information whose disclosure would:
 - (A) interfere with enforcement proceedings
 - (B) deprive a person of a fair trial
 - (C) constitute an unwarranted invasion of personal privacy
 - (D) disclose confidential sources
 - (E) disclose investigation techniques
 - (F) endanger life or physical safety of an individual
- (b)(8) Prepared by or for a government agency regulating or supervising financial institutions
- (b)(9) Geological and geophysical information and data, including maps, concerning wells

Other Grounds for Withholding

NR Material not responsive to a FOIA request excised with the agreement of the requester

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From:	"SMART Core" <svcsmartbtsewshprec1@state.gov></svcsmartbtsewshprec1@state.gov>
	(b)(6)
	Fritz, Jonathan D (b)(6)
CC.	(b)(6)
CC:	
Subject:	PRC Making Progress in Race to Develop a COVID-19 Vaccine
Date:	Tue, 25 Aug 2020 08:54:38 +0000

UNCLASSIFIED SRH



Info Office: IRO_DIR, EB_EAP, FAO_EAP

MRN: 20 BEIJING 1512

Date/DTG: Aug 25, 2020 / 250851Z AUG 20

From: AMEMBASSY BEIJING

Action: WASHDC, SECSTATE ROUTINE

E.O.: 13526

TAGS: TSPL, PGOV, PREL, SENV, SHLH, TBIO, TPHY, SCUL, OEXC, KPAO,

FDA, HHS, NSF, CN

Captions: SENSITIVE

Reference: 20 SAO PAULO 390

Subject: PRC Making Progress in Race to Develop a COVID-19 Vaccine

1. (SBU) Summary and Comment: Chinese biomedical companies CanSinoBIO, Sinopharm and Sinovac Biotech have developed three out of six of the COVID-19 vaccine candidates worldwide that have been approved to begin phase III clinical trials, the final step required by most regulatory organizations to secure official approval for public use. Given the low rate of COVID-19 infection in China, Sinopharm and Sinovac Biotech began phase III clinical trials overseas in July, making them the only two Chinese companies to enter the final phase of human testing for a COVID-19 vaccine. Despite not having yet undergone phase III clinical trials, CanSinoBIO's vaccine candidate received one-year special approval for military use from the Central Military Commission (CMC) Logistic Support Department Medical Services Directorate. Sinopharm also began to vaccinate employees of state-owned enterprises and atrisk members of the Chinese public. Some Chinese public health contacts have expressed uncertainty about the potential effectiveness of Chinese vaccine candidates, speculating the coronavirus may mutate over the fall and winter months making it more resistant to vaccine treatments. While senior PRC officials have vowed to share COVID-19 vaccines as "global"

public goods" – notably with low- and middle-income countries – experience gained during the 2009 H1N1 pandemic showed that high income countries negotiated advanced orders of vaccines, which crowded out low-income countries from the market. Subsequent donations from high-income countries were only made after they had covered their own populations. It remains to be seen if and how China follows through on donating PRC-produced vaccines to other countries while having to cover its own massive population. End Summary and Comment.

Chinese Biomedical Companies Lead in COVID-19 Vaccine Development

2. (SBU) Chinese biomedical companies are making significant progress in global vaccine development efforts to treat COVID-19. According to the World Health Organization, eight out of over twenty vaccines for COVID-19 currently in human clinical trials around the world are being developed in China. Most of these Chinese vaccine candidates are in phase I and II of clinical trials, although three have already been approved to enter phase III, the final step required by most regulatory organizations to secure official approval for public use. To date, only six vaccine candidates worldwide are in phase III trials. [Note: Phase I trials involve groups ranging from 20 to around 100 patients to check a vaccine for negative side effects. Phase II trials include hundreds of patients who are tested to determine the safety and efficacy of the vaccine. Phase III trials contain thousands of participants who are tested to better understand the effectiveness of the vaccine, the benefits, and the range of possible adverse reactions. End Note.] Four Chinese biomedical companies relied on well-established technology to create inactivated vaccines, which contain killed virus particles meant to induce an immune response in the vaccine recipient. In addition, the People's Liberation Army (PLA) was working with Chinese vaccine developer Walvax Biotechnology to explore new technology that could produce mRNA vaccines using a synthetic version of the genetic code that the coronavirus uses to form proteins designed to induce immunity.

CanSinoBIO Developed the First Chinese Vaccine Candidate

3. (SBU) Chinese biomedical company CanSino Biologics Inc (CanSinoBIO) developed the first vaccine candidate against COVID-19 in China – known as Ad5-nCoV – in collaboration with the Beijing Institute of Biotechnology, which is subordinate to the PLA Academy of Military Science (AMS) Academy of Military Medical Sciences (AMMS). [Note: Ad5-nCoV is a viral vector vaccine that uses a harmless virus called adenovirus type-5 (Ad5) to carry genetic material from the novel coronavirus (nCoV) into the body to induce an immune response. End Note.] PLA Major General Chen Wei, a top epidemiologist and virologist at AMMS who led the phase I clinical trial for Ad5-nCoV, reported the vaccine candidate results were encouraging and had no "serious" side effects, but admitted more research needed to be done. On March 20, Chen was reportedly the first to be injected out of 108 volunteers. Neutralizing antibodies increased significantly among the 108 participants at day 14 and peaked 28 days postvaccination. [Note: Neutralizing antibodies are part of the body's immune response that protects against infections. End Note.] Moreover, no serious adverse events were noted within 28 days post-vaccination. However, some vaccine recipients reported mild to moderate symptoms including fever (54 percent), while patients also experienced fatigue (44 percent), headaches (39 percent), and muscle pain (17 percent). Results from phase II trials begun in April with 508

participants from Wuhan found that the Ad5-nCoV vaccine was safe and induced significant immune response of neutralizing antibodies at day 28 in the majority of recipients after a single immunization.

4. (SBU) At that time, CanSinoBIO still needed to broaden its testing pool to conduct phase III trials and determine the effectiveness of the vaccine before it could be licensed for public use in China. However, the low rate of COVID-19 infections in China made it difficult to conduct large-scale domestic vaccine trials, stated Chinese public health experts. Consequently, CanSinoBIO partnered with the National Research Council of Canada in May and was preparing to conduct phase III clinical trials of Ad5-nCOV with Canadian volunteers in the near future. CanSinoBio also entered discussions with Russia, Brazil, Chile, and Saudi Arabia about launching phase III human clinical trials among their populations, said CanSinoBio co-founder and executive director Qiu Dongxu on July 11. On August 9, Saudi Arabia announced phase III clinical trials on around 5,000 people would begin soon using CanSinoBio's vaccine candidate while discussions remain ongoing in the other three countries. Separately, Mexico signed a memorandum with CanSinoBio and Walvax Biotechnology to conduct human testing trials of Ad5-nCoV between September and January 2021, said Mexican Foreign Minister Marcelo Ebrard during an August 11 news conference. On the same day, the PRC National Intellectual Property Administration issued China's first COVID-19 vaccine patent approval to CanSinoBio for Ad5-nCOV. CanSinoBio Executive Director Oiu revealed that 40,000 volunteers would be recruited for upcoming trials and a new factory in China with the capacity to produce 100-200 million doses of COVID-19 vaccines per year by early 2021 was under construction.

Sinopharm and Sinovac Biotech Enter Phase III COVID Trials

5. (SBU) The state-owned China National Pharmaceutical Group (Sinopharm) and Sinovac Biotech began phase III clinical trials overseas in July, making them the only two Chinese biomedical companies to-date to enter the final phase of human testing for a COVID-19 vaccine. Sinopharm Chairman Liu Jingzhen told a state-run media outlet in late May that 180 recipients of Sinopharm's inactivated vaccine candidate, including himself, developed antibodies with a 100 percent protective rate against COVID-19 during phase I clinical trials. Following phase II clinical trials on more than 1,000 volunteers, Sinopharm released an official statement in late June saying the vaccine candidate was safe and effective with adverse reactions far lower than other vaccines undergoing trials. Phase III trials were currently underway in the United Arab Emirates with around 15,000 participants as of July 15 using two different inactivated vaccine types. Sinopharm also announced in late July an agreement with Parana Technology Institute (Tecpar) to begin vaccine trials in Brazil soon. In Bahrain, phase III clinical testing was scheduled to begin on August 10 with 6,000 volunteers over the next 12 months, reported the Bahrain Ministry of Health. Sinopharm announced August 20 that Peru, Morocco, and Argentina approved phase III clinical trials on volunteers in their countries. During a July 22 interview, Sinopharm Chairman Liu estimated phase III trials would be completed in three months. [Note: Following completion of the phase III clinical trial, the company would need to apply for regulatory approval before the product would be available to the domestic market. **End Note**.] Partnering with Sinopharm, the Beijing Biological Products Institute and the Wuhan Institute of Biological Products both developed two different inactivated vaccines that were expected to be available by the end of December at the price of

RMB 1,000 (USD 144). Sinopharm was also preparing to expand its annual production capacity to a combined 220 million vaccine doses.

6. (SBU) Chinese vaccine developer Sinovac Biotech also produced an inactivated vaccine candidate called CoronaVac that has entered phase III human testing trials and is projected to begin production early next year. [Note: During the outbreak of SARS in 2003, Sinovac was the only Chinese firm to enter phase I vaccine trials; however, research ended following the SARS pandemic. Sinovac was able to build on this earlier research given the similarity between COVID-19 and SARS. End Note.] Sinovac said phase I and II trials for CoronaVac showed favorable immunogenicity and safety profiles, and no severe adverse events were reported. Sinovac Biotech experts noted that two doses of the vaccine candidate were needed to immunize one person, but observed the reduction of neutralizing antibodies 14 days after the vaccination. [Note: There are still knowledge gaps about COVID immunity; however, reduction in neutralizing antibodies may suggest a possible waning of immunity over time. End Note.] Sinovac Biotech had already begun phase III clinical trials by July in Brazil and committed to sharing 60-100 million doses through a collaboration with São Paulo-based Instituto Butantan (Ref A). Sinovac Biotech CEO Yin Weidong disclosed on July 11 that his company was "actively in discussion with several countries" in Asia, including Indonesia, Turkey, and Bangladesh, about conducting phase III trials and was exploring options to carry out human trials in Europe. Since then, the Bangladesh Medical Research Council (BMRC) approved phase III clinical trials on July 22, which were to be conducted by International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) on 4,200 volunteers in seven hospitals specialized in COVID-19 treatment. Indonesian state-owned company Bio Farma also partnered with Sinovac Biotech and began carrying out phase III clinical testing on August 14 that will ultimately involve as many as 1,620 patients in Indonesia. Yin explained that Sinovac Biotech aimed to produce 300 million doses per year.

PRC Authorities Approve Vaccine for Special Use

- 7. (SBU) Despite not having undergone phase III clinical trials, the Central Military Commission (CMC) Logistic Support Department (LSD) Medical Services Directorate issued one-year special approval for CanSinoBIO's Ad5-nCOV as a "military-specially-needed drug" on June 25. With this special designation and approval, CMC could begin pharmaceutical production of Ad5-nCoV solely for limited military use among Chinese armed forces. [Note: Major General Chen Jingyuan, the Director of the CMC LSD Medical Services Directorate, announced during a March 3 press conference that the Chinese military has reported zero cases among its personnel. End Note.]
- 8. (SBU) With approval from the State-owned Assets Supervision and Administration Commission of the State Council, Sinopharm also began inviting employees of state-owned enterprises to take the vaccine. More than 1,000 Sinopharm employees were voluntarily vaccinated without any adverse effect, reported the biomedical company in June. China TravelSky, a Chinese state-owned civil aviation and information technology company, prioritized its research and development (R&D) staff and airport terminal workers for vaccination, but also offered to vaccinate overseas travelers, medical staff members involved in COVID-19 prevention efforts, and residents from medium and high-risk communities in

Beijing. Media reports also indicated that PetroChina employees were asked to take the Sinopharm vaccine. Separately, Chinese Center for Disease Control and Prevention (China CDC) Director Gao Fu revealed during a webinar on July 26 that he had been injected with an experimental COVID-19 vaccine. Gao explained, "Everybody has suspicions about the new coronavirus vaccine. If even we didn't do it, how can we persuade...the public to be vaccinated." Gao refused to disclose details about the vaccine he took, saying he did not want to appear to be "doing some kind of propaganda." [Note: Gao coauthored a paper in June on an "inactivated" vaccine candidate developed by SinoPharm leading some to speculate he was injected with the same vaccine. End Note]. However, a few Chinese public health contacts expressed doubts over the effectiveness of Chinese vaccine candidates, speculating that the coronavirus may mutate over the fall and winter months making it more resistant to vaccine treatments. [Note: If this problem were to occur, the impact would not be limited to Chinese vaccine candidates. End Note.]

Senior Chinese Leaders Pledge to Share Vaccines

9. (SBU) Chinese Communist Party Chairman Xi Jinping announced on May 18 during a virtual speech to the World Health Organization that China would make its COVID-19 vaccine a "global public good" ensuring it is accessible and affordable in developing countries. Subsequently, PRC Foreign Minister Wang Yi said in late July that China pledged a \$1 billion loan to help Latin American and Caribbean countries access COVID-19 vaccines once available during a virtual conference with his Latin American counterparts. China CDC Director Gao also emphasized during a July 31 virtual seminar that the vaccine needed to be shared in low and middle-income countries unable to afford it. On August 24, Premier Li Keqiang Li stated during the third leaders meeting of the Lancang-Mekong Cooperation (LMC) organization that any Chinese-produced COVID-19 vaccine would be provided to Mekong countries "on a priority basis."

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	ESTH: (b)(6) (Guangzhou)
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	COMMERCE WASHINGTON DC ROUTINE; NATIONAL SECURITY

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COUNCIL WASHINGTON DC ROUTINE; CHINA POSTS

COLLECTIVE ROUTINE; ENVIRONMENT SCIENCE AND TECHNOLOGY

COLLECTIVE ROUTINE

XMT: CHENGDU, AMCONSUL; CARACAS, AMEMBASSY; ST PETERSBURG,

AMCONSUL

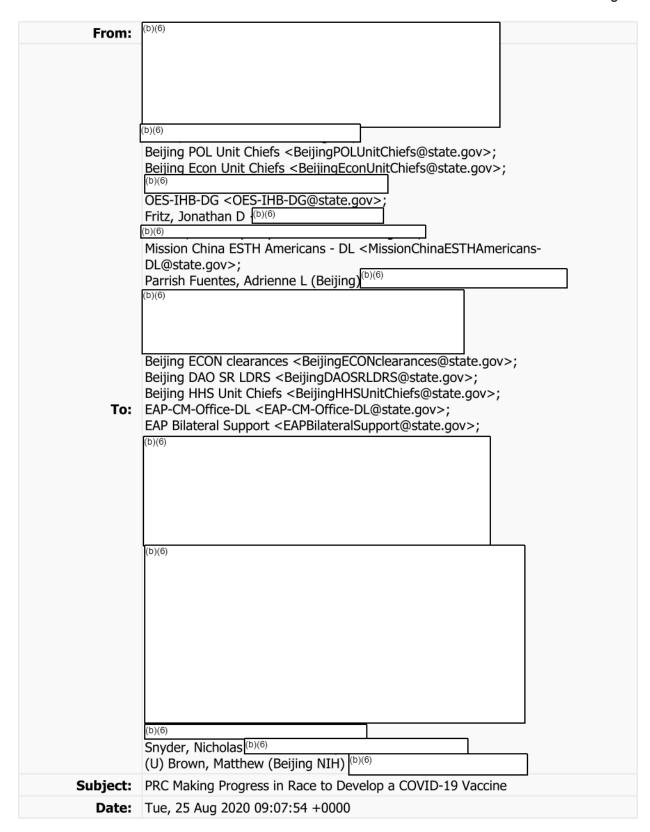
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Dissemination Rule: DIS_IRO_DIR, DIS_EB_EAP, DIS_FAO_EAP

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SBU

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Cable sent.

All the best,

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(b)(6)

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From: SMART Core <svcsmartbtsewshprec2@state.gov>

Sent: Tuesday, August 25, 2020 4:54 PM

To:(b)(6)

Subject: PRC Making Progress in Race to Develop a COVID-19 Vaccine

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Action Office: ECON, MGT, RSO, POL, PAS, SCIENCE

Info Office: MED_INFO, EXEC_INFO, MGT_INFO, RSO_INFO, DAO_INFO,

SCIENCE_INFO, ECON_INFO, POL_INFO

MRN: <u>20 BEIJING 1512</u>

Date/DTG: Aug 25, 2020 / 250851Z AUG 20

From: AMEMBASSY BEIJING

Action: WASHDC, SECSTATE ROUTINE

E.O.: 13526

TAGS: TSPL, PGOV, PREL, SENV, SHLH, TBIO, TPHY, SCUL, OEXC, KPAO,

FDA, HHS, NSF, CN

Captions: SENSITIVE

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04/24/2023 Page 9

COVID-19 infection in China, Sinopharm and Sinovac Biotech began phase III clinical trials overseas in July, making them the only two Chinese companies to enter the final phase of human testing for a COVID-19 vaccine. Despite not having yet undergone phase III clinical trials, CanSinoBIO's vaccine candidate received one-year special approval for military use from the Central Military Commission (CMC) Logistic Support Department Medical Services Directorate. Sinopharm also began to vaccinate employees of state-owned enterprises and atrisk members of the Chinese public. Some Chinese public health contacts have expressed uncertainty about the potential effectiveness of Chinese vaccine candidates, speculating the coronavirus may mutate over the fall and winter months making it more resistant to vaccine treatments. While senior PRC officials have vowed to share COVID-19 vaccines as "global public goods" - notably with low- and middle-income countries - experience gained during the 2009 H1N1 pandemic showed that high income countries negotiated advanced orders of vaccines, which crowded out low-income countries from the market. Subsequent donations from high-income countries were only made after they had covered their own populations. It remains to be seen if and how China follows through on donating PRC-produced vaccines to other countries while having to cover its own massive population. End Summary and Comment.

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"UNCLASSIFIED"

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