

**URGENT REQUEST CONCERNING DRUG AND VACCINE DEVELOPMENT
AGAINST COVID-19 AND EMERGING INFECTIOUS DISEASES (PART 4)**

**June 5, 2020
Shizuoka Prefecture**

The coronavirus disease (COVID-19) that has been ravaging Japan and the world is a crisis for humanity. Infectious disease control and prevention is an issue of national security. Conventional forms of national security are self-defense to deter foreign aggression and terrorism and disaster preparedness to reduce the effects of natural calamities. We must now recognize that national security today involves self-defense, disaster preparedness, and infectious disease control and prevention.

From a national security perspective, the Government of Japan has the responsibility to domestically develop and manufacture drugs and a COVID-19 vaccine without delay to restore a sense of security. Japan's responsibility to the international community is great as host for the upcoming Tokyo Olympic Games.

The Japanese Diet enacted the government's second supplementary budget, which allocated 205.5 billion yen toward vaccine and drug development. Unfortunately, this is inadequate. The research and development of a single drug or vaccine could cost up to 100 billion yen, yet this costly investment does not guarantee success. Compared to the United States and China, Japan has already fallen behind the race to develop a COVID-19 vaccine and treatment. It is high time for the Japanese government to establish a lasting R&D framework and bolster our mass manufacturing capacity for rapid production.

Professor Okazaki Tetsuji of the University of Tokyo has endorsed Shizuoka Prefecture's previous urgent requests to the Japanese government regarding the establishment of a one-trillion-yen nationally-funded development fund to fight emerging infectious diseases. He further proposed: "Half of the fund should be spent now as an emergency measure to fight COVID-19 and manage the remaining 500 billion yen to yield over 10 billion yen per year on a two to three percent interest rate. This would sustainably generate R&D funds into the future." His remark demonstrates confidence in Japan's ability to develop new drugs and vaccines.

Japan's pharmaceutical companies and research laboratories are highly competent, yet they lack resources, leaving them cautious with their R&D spending. Domestic

production of pharmaceutical drugs and medical supplies should be identified as a national economic security strategy, and research entities and pharmaceutical companies should be encouraged to explore their R&D ventures more audaciously. Japan's life science is one of the best in the world, and it is our duty to do our part not only for the benefit of the Japanese public but also for the benefit of humanity.

Shizuoka Prefecture once again strongly requests the Government of Japan to establish a one-trillion-yen drug and vaccine development fund for emerging infectious diseases (hereinafter, the fund), which could be drawn from the 10 trillion yen reserve fund under the second supplementary budget. This would enable early development of drugs and vaccines against new infectious diseases, starting with COVID-19, as well as spur innovation.

The scheme for the new fund is suggested as follows:

1. The fund will operate under the premise that it will be exhausted.
2. Japanese universities, research institutes, and pharmaceutical companies are invited to apply for the fund. Those selected will each receive up to 10 billion yen for research and development. (Professor Honjo Tasuku's emergency proposal made available on his website on April 16, 2020 urged the Japanese government to inject 10 billion yen for emergency research and called for all researchers and scientists to unite to immediately conduct COVID-19 pathology analysis and identify treatment options.)
3. The grantee of the fund will conduct and report outcomes of their basic research and non-clinical study.
4. After a rigorous review of the findings, the top three proposals will each receive additional funding of up to 100 billion yen to conduct clinical trials and develop and produce drugs and/or vaccines.
5. Basic research and non-clinical study connect research bodies with pharmaceutical companies. It is suggested that the review of the proposals be led by Professor Yamanaka Shinya (2012 Nobel Laureate), Professor Omura Satoshi (2015 Nobel Laureate), and Professor Honjo Tasuku (2018 Nobel Laureate).
6. The grantee of the fund agrees in advance to partially waive its royalty payments in the event of a successful production of a new drug and/or vaccine. The Japanese

government will purchase them upon consideration of the R&D and production cost. These will be donated to hospitals and developing countries, free of charge, and all countries that request the new drugs and/or vaccines will receive access. Advanced countries will be able to make their purchases from pharmaceutical companies.

7. The remainder of the fund will be used in the future when the need to develop drugs and vaccines against a newly emerged infectious disease arises.
8. Given the nature of this emergency and from a national strategy perspective, the fund will be managed by the economic division of the National Security Secretariat, Cabinet Secretariat, and not by the current Japan Agency for Medical Research and Development.
9. Clinical tests and screening procedures will be fast-tracked to expedite the product development of new drugs.

Note:

This urgent request is based on comments made by Governor Kawakatsu Heita during the National Governors' Association video conferences on April 17, April 29, May 12, May 20, and June 4, 2020. As a result, the content of this request was incorporated into the National Governors' Associations' set of recommendations proposed to the Government of Japan.

Copies of these requests were sent to experts and leaders in the medical and research fields to gain their perspectives on establishing such fund. Nobel laureate Professor Honjo Tasuku, President Yokokura Yoshitake of the Japan Medical Association, among others, have responded favorably and voiced their support.