Toward Prevention of Biohazards

For Human Rights in the Age of Emerging New Pathogens and Biotechnology

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1. Preface

1.1 In a previous paper of mine (Shibata, 1996b) I described the implications of the nuclear age for not only Japanese but also whole humanity including the nations of the nuclear Big Five powers. In that paper I also shed light on the destiny of atomic victims of Hiroshima and Nagasaki who were treated as human guinea pigs by US and Japanese governments, especially the Atomic Bomb Casualty Commission (ABCC) and Japan's National Institute of Health (JNIH). I further revealed the fact that American citizens were also victimized as human guinea pigs by their own government, especially the scientists who served the Manhattan Project, the nuclear industry and the so-called Military-Industrial Complex.

1.2 In this paper I will raise questions about the implications of the age of emerging new pathogens and biotechnology for whole humanity. I will describe not only the origin and development of the civil rights campaigns against unregulated laboratories of pathogens and genetically modified organisms (GMOs), including the JNIH-in 1997 renamed National Institute of Infectious Diseases (NIID), but also the theoretical background of the campaigns from the standpoint of environmental sociology, environmental science and law, and the science of safety, especially biosafety, as well as the theory of human rights and bioethics.

1.3 It was in July of 1986 when the JNIH made public its plan to move to a small site in one of the most populated residential areas in Tokyo. The planned site is adjacent just to many houses, housing complexes, two welfare facilities for handicapped persons, Waseda University (WU) with tens of thousands of students, a major

hospital and the legally designated sites for refugees in the case of emergency including a big earthquake and/or fire. First, the JNIH did conceal from the residents around the site the fact that it would deal with various kinds of dangerous pathogens, GMOs, a large quantity of organic solvents and radioisotopes as well as tens of thousands of lab animals. In the end of the same year we knew this fact.

1.4 Such a situation motivated me to start to study almost all major books and papers, which were written by scientists, including the leading staff of the JNIH, on the risk and/or "safety" of such a laboratory. As cited later, I was shocked to read them. Then, since January of 1987, together with my colleagues and friends, I have continued to raise lots of questions about the "safety" and location issues of the JNIH to the directors of it and asked them to reply to ours. To our surprise, they could neither sincerely answer to ours, nor scientifically explain the reasons why they thought that such a laboratory located in such a site would be "safe" and "appropriate" to residents and the public. Nevertheless, *the JNIH has insisted not only that such laboratories could be set up anywhere, but also that as their work is "city-oriented research," they should be located in populated areas.* The JNIH further insisted that such laboratories in such areas were "absolutely safe" not only to their staff but also to the residents and the public. According to the JNIH, such laboratories and facilities do not have to do any risk assessment, including environmental impact statement (EIS).

1.5 As a result, the civil rights campaign against the planned location of the JNIH started. Since then, over ten years have passed. Many citizens, handicapped persons, professors of WU and their

students have been involved in this campaign. It has also been supported by not only many concerned scientists, including microbiologists, entomologists, meteorologists, environmental scientists, mathematicians, a designer of the Level 3 laboratory, an expert in HEPA filtration, experts in environmental law and human rights, and lawyers, but also major human rights organizations of environmental and ecological protection as well as major trade unions in this country.

1.6 Many critical comments and articles on the wrong location of the JNIH have been published and reported in the mass media in Japan. Now it is regarded one of the most controversial environmental, political and social issues in this country.

1.7 It has further found many international repercussions. In November 1991 Mr. Jeremy Rifkin, an American ecologist and author of international repute, visited Tokyo to observe the site of construction of the JNIH laboratory, and said, "The location of JNIH is crazy and shocking. It is the worst in the world. Supporting with an international campaign we have to stop their experiments." The articles on the location and misdeeds issues of the JNIH appeared also in journals such as *Nature* (London), *International Perspectives in Public Health* (Toronto), a German bioethical monthly *GID* (Berlin) and others.

1.8 Supporting the campaign against the wrong location of the JNIH, the "International Appeal toward Prevention of Biohazards" was issued in 1994. Its re-titled second version, "International Appeal toward Prevention of Hazards which might be brought from JNIH-NIID" (1997) reads:

"We, the undersigned, support the campaign against the present

location and experiments with pathogens of the NIID in Shinjuku-ku, Tokyo, one of the city's most densely populated residential areas."
"We believe that NIID must respect international regulations, including those of the WHO and the EC (EU) as well as national regulations such as "The Genetically Modified Organisms (Contained Use) Regulations of 1992" of the UK. All experiments at NIID should be halted and it should be relocated to another, unpopulated site."
It has been endorsed by many scholars, including two scientists of the NIID as well as scientists and ecologists of international reputation. They include: Dr. H. Arai, Senior Researcher, NIID, Tokyo; Dr. R. Bertell, President, International Institute of Concern for Public Health, Toronto; Dr. C.H. Collins, Collaborating Editor of WHO's *Laboratory Biosafety Manual* (2nd edition, 1993) and WHO's *Safety in Health-care Laboratories* (1997), Kent, UK; Prof. em. S. Harris, California State Univ., Calif.; Dr. S. Honjo, Honorary Fellow of NIID and Prof. of Aichi Univ., Nagoya; Prof. S. Ichikawa, Saitama Univ., Urawa; Prof. D. McLellan, Univ. of Kent, Kent, UK; Prof. em. H.L. Parsons, Bridgeport Univ., Conn.; Prof. A. Rapoport, Univ. of Toronto, Toronto; Mr. J. Rifkin, President, Foundation on Economic Trends, Washington, D.C.; Dr. A. Sibatani, ex-President, Kyoto Seika Univ., Kyoto; Prof. A. Tominaga and Prof. K. Urata, Waseda Univ., Tokyo and Prof. em. G. Wald, Harvard Univ., Cambridge, Ma., and Nobel Laureate in Physiology/Medicine 1967.

2. Why did the JNIH refuse to make public the information about the classification of risks of pathogens?

2.1.1 As to the risk of laboratories dealing with infectious microorganisms, already in 1982, Dr. Takashi Kitamura, one of the leading staff of the JNIH, warned: "In the recent years it turned out that there was a general tendency that laboratories of microorganisms would be the biggest source of infections among the public" (Kitamura, 1982).

2.1.2 The representative book on prevention of biohazards edited by the leading staff of the JNIH also warned: "It turned out that there was a strong tendency of rising probability of laboratory-acquired infections by mass culture of pathogens. As seen in the case of tumor viruses and GMOs, there is a possibility of biohazards which cannot be predicted by the hitherto experienced standards of pathogenic microbiology" (Oya, Kitamura et al., 1981, p.1).

2.1.3 It continued: "It is considered that there is a possibility of the existence of a carcinogenic nature in almost all DNA viruses. It is proved that there is carcinogenic property among those viruses classified as RNA tumor viruses, too" (ibid., p. 41).

2.1.4 When our campaign started, the leading staff of the JNIH said that it would not more mainly deal with pathogens, because the threat of pathogens was almost overcome, and that it would hereafter rather concentrate on research of cancer, Alzheimer disease and so on. We insisted that the JNIH would be intensively forced more to deal with new unknown pathogens, because lots of them would appear in such a age of biotechnology. The degree of risk and characteristics of such pathogens would be understood, only after humans will be infected with them. When an outbreak of them would occur, it would be too late for the infected to be treated. Therefore, we asked the reason why such pathogens should be

cultured and tested in residential areas. Of course, the leading staff of JNIH could not explain it to us. As a matter of fact, it turned later out that since the end of the 1980s many new pathogens appeared and outbreaks of them often occurred here and abroad.

2.2.1 In this context, we paid much attention to the concept "the risk of pathogens" defined by the JNIH. According to the WHO manual (1st edition, 1983 and 2nd edition, 1993),

"Each country should draw up a classification by risk group of the microorganisms encountered within its boundaries, based on the following factors:

- Pathogenicity of the organism.
- Mode of transmission and host range of the organism. These may be influenced by existing levels of immunity, density and movement of the host population, presence of appropriate vectors and standards of environmental hygiene.
- Availability of effective preventive measures.
- Availability of effective treatment...

"In assessing the various criteria for classification it is also important to take into account *conditions prevailing in the geographical area in which the microorganisms are handled.*" (WHO, 1993, pp. 2-3, emphasis added. The author's note: I often used to refer to the 1st edition, but in this paper, I refer to the 2nd edition. I will apply the same principle, when I refer to other books, too.)

2.2.2 Dr. C.H. Collins is a British microbiologist of international repute and well known as an author of his famed book, *Laboratory-acquired Infections* (3rd ed., 1993) as well as a collaborating editor of two books from the WHO (see, 1.8 above). In the first book, he writes: "An organism which offers no particular hazards to the

community in one district may pose serious problems and require more precautions in another, because of the presence of potential vectors and reservoirs of infection...Classifying microorganisms on the basis of hazard is obviously not an exact science" (Collins, 1993, pp. 45-46).

2.2.3 Most pathogens of level 1 and 2 have been considered not so dangerous, but for the past several years some of them have been found to be not only dangerous but also fatal (Wright, 1990, J. Culliton, 1990, Anderdon, 1991, Morse, 1993, Knight, 1993, Lederberg, 1994, Murphy, 1994, Satcher and Fauci, 1994, Hughes and La Montagne, 1994, Cassell, 1994).

2.2.4 In addition, as we understand it, a safety standard of leaked GMOs, DNAs, rDNAs and tumor viruses has still not been clarified. The Health and Safety Executive (HSE) of the UK government also warned researchers and the public of the carcinogenic risk of naked DNAs. According to it, to deal with naked DNAs should be considered to be more dangerous than the *HIV* (Brown, 1990). Besides, many kinds of leaked viruses, even when they could be deactivised, would have the carcinogenic properties (Oya, Kitamura, et al., 1981). So, we have been afraid that in dozens years there would probably be a higher percentage of cancer among residents around the JNIH.

2.3 Therefore, we asked the JNIH to make public any information about the hitherto accepted official classification of infectious microorganisms *in the concrete geographical conditions at the new site, as well as the safety standard of these pathogens and GMOs for residents, including babies, pregnant women, the aged, handicapped and those who have immune-deficiency syndrome.*

But, to our surprise, the JNIH has arrogantly continued to refuse to answer all these questions.

3. Why exhaust air into a densely populated area from laboratories where pathogens are handled and from biotechnology laboratories?

3.1 In Japan, since the beginning of the 1980s the so-called physical containment devices and facilities, including Biological Safety Cabinets (BSC) and the Level 2 and 3 Laboratories, have been widely used for experiments dealing with pathogens and GMOs. Generally speaking, these equipment is useful and necessary for safety of researchers, but not always so to the residents around it, when it is located in residential areas.

3.2.1 Accordingly, the WHO manual warns: "Exhaust air from the laboratory (other than from biological safety cabinets) must be discharged directly to the outside of the building so that it is dispersed away from occupied buildings and air intakes...The exhaust air from Class I or Class II biological safety cabinets, which will have been passed through HEPA filters, must be discharged directly or through the building system to the outside air" (WHO, 1993, pp. 20-21).

3.2.2 The above cited book edited by the leading staff of the JNIH also warned: "It is technically very difficult to design, inspect and manage the exhaust system of Level 3 laboratories. In addition, their running cost is very much expensive...Exhaust air from the laboratory should not be reused without appropriate decontamination process... Vents of exhaust air should be placed on the building roof so that it is not reused by the neighboring area" (Oya, Kitamura,

et al., 1981, p. 46).

3.2.3 Dr. Shigeo Hino (then Assistant Professor at Medical School, Nagasaki University) is regarded as one of the most excellent experts in the field of HEPA filtration. His warning is as follows:

3.2.3.1 "As the study of tumor viruses has been intensified since the 1960s, possible biohazards not only for staff of laboratories *but also for residents living around them* have attracted special attention. The difference between tumor viruses and other pathogens has received much attention, because it would take many years from infection to disease in the case of tumor viruses, and it would be fatal when the disease would be discovered. In any case, it is very difficult to negate such 'possibility'" (Hino, 1983-4, p. 649, emphasis added).

3.2.3.2 "Even nowadays in Japan one of three to ten HEPA filters on the market with a certificate of tested safety is found to be defective. In Japan most of HEPA filters in medical-biological laboratories are used without any in-place testing after purchase. They are installed in a system or mechanism where any in-place testing is impossible" (ibid., p. 650).

3.2.3.3 "It is said that 10 to 30% of HEPA filters with a certificate of tested safety are found to be defective when in-place testing is performed after purchase. It seems that the quality control is incredibly poor, as far as HEPA filters are concerned" (ibid., p. 654).

3.3 In this context it is natural that there is no scientific paper which insists that exhaust air from Level 3 laboratories may be re-circulated into occupied buildings and reused or breathed by neighboring residents around the laboratories. As a matter of fact,

the so-called "physical containment equipment" should be called "the physical non-containment equipment discharging deadly agents."

3.4 In our case, just outside the building of the JNIH there are so many buildings and housing complexes occupied by residents, handicapped people and patients, as well as students and staff of WU. As a result, whereas the staff of the JNIH-NIID do not have to breathe the exhaust air, the residents (including many immune-deficient people), handicapped people and patients of a major hospital, as well as tens of thousands of students and staff of WU cannot but breathe it. We do not like to have our residents, children and grand-children breathe the emissions of infection and/or cancer-causing microorganisms in exhaust air from the JNIH laboratory. We do not think such a site of the JNIH laboratory is appropriate in the residential area. If someone says it is "appropriate," we have to ask him/her to give us the reason and to make an Environmental Impact Statement (EIS) of it available to the public.

3.5 In this section I have raised several questions about the "safety" or more exactly risk of the so-called "physical containment." As to the so-called "biological containment" I think that several questions about the "safety" or rather risk of it remain still unanswered. It is too much specific and not appropriate for us to discuss the problems in detail here. So, I would like to confirm only that the hypothesis on the "biological containment" is still problematic (Bouma and Lenski, 1988, Bielecki, et al., 1990, Third World Network, 1996).

3.6 In connection with possibilities of environmental risk which may be brought from laboratories of pathogens and GMOs, one of the urgent tasks for concerned scientists and the public is to develop a

scientific methodology of environmental risk assessment of pathogen and engineered organisms. To my knowledge, there is no scientific methodology of it. According to an expert in the field of science of environment, "Although applicable pathogenicity tests exist, the probability of undesired pathogenicity cannot be predicted either before or after testing" (Suter II, 1985, p. 218).

3.7 Recently, an increasing number of scientists are questioning the scientific validity of the basic premises of genetic engineering. Once unknown GMOs have escaped from the so-called containment laboratory in populated areas, they would migrate, mutate and multiply in an uncontrollable manner with unpredictable harmful effects. They cannot be recalled if later found to have pathogenicity (Third World Network, 1995, 1996 and Mae-Wan Ho, 1997). Therefore, I think that it is neither scientific nor appropriate for the leading staff of JNIH to insist that it is "absolutely safe" in the most populated residential area.

4. Why are many chemicals, radioisotopes, lab animals, insects and infectious waste handled in a densely populated area?

4.1.1 We had the same questions about the so-called safety of exhaust air from JNIH which includes the chemicals and radioisotopes.

4.1.2 According to the "Fundamental Act of Construction" in Japan, even a small chemical factory with several workers is not allowed to be set up in a residential area. However, the JNIH is like a huge experimental factory with several hundreds workers. There are lots of chemicals including organic solvents and carcinogenic chemicals.

We felt doubtful about the safety of chemicals in exhaust air from the JNIH.

4.1.3 Besides, explosion and fire occurred at least six times during the past forty years inside the JNIH's old buildings located at the larger sites in Shinagawa-ku, Tokyo and Musashi-murayamashi City in a suburb of Tokyo. Most of them occurred in daytime and could fortunately be extinguished by the staff. Of course, there are possibilities of explosion and fire inside the present laboratory of JNIH which is located at such a small site adjacent to houses. Suppose a fire or explosion at the laboratory in the middle of the night under a strong wind. In night there are no staff of JNIH except some part-time guards dispatched by a security company who have nothing to do with fire and explosion in such a laboratory. In this case, we fear that a number of houses may be burnt down by fire spreading from JNIH.

4.2 We also doubted the safety of radioisotopes in exhaust air from JNIH. In Japan only density is regulated, while total amount of radioactive substances in exhaust air is not. Since there are so many radioisotopes (RI) laboratories in JNIH, the amount of radioactive substances in exhaust air from JNIH must be large. As far as RI laboratories are concerned, they are inspected only once a year by a governmental agency with a prior notice. Therefore we think that there would be a possibility of environmental disturbance brought about by exhaust air from many RI laboratories at JNIH.

4.3.1 According to WHO, "All laboratory animals can be symptomless carriers of microorganisms highly dangerous to man" (WHO, 1983, p. 23). This proposition is not contained in its 2nd edition (WHO, 1993), but we think it is still valid today in the light of biohazards

experienced in Japan. The *Asahi Journal* (16 September 1988), one of the leading weeklies, reported that in the 1980s a mouse was found at a kindergarten adjacent to the laboratory of JNIH at the old site in Shinagawa-ku. So we also assumed that lab animal(s) escaping from JNIH might bring a risk to health of our residents.

4.3.2 As to potential vectors and reservoirs of infection, we predicted that there would be lots of cockroaches and fleas inside and outside JNIH. In addition, we said that there were many homeless cats around the site of JNIH. For example, there are many fleas in the bushes and on roads around JNIH. When I walk my dog around JNIH for only ten minutes or so in the hot season from June to September, it is usual to find later over ten fleas in the dog's hair. These fleas don't bite humans, only dogs. It is quite possible that fleas would go in and out of JNIH with shoes and/or trousers of staff, when they would go to restaurants in the neighboring shopping areas.

4.3.3 We also feared that there would be many, many cockroaches in the new laboratories of JNIH. In addition to these common cockroaches, some special species of cockroaches are known to be bred and researched in the laboratory of entomology at the same building of JNIH. For example, "the species of cockroaches that cannot be exterminated by any strong insecticide sprinkled everyday," and "ones that can reproduce themselves only by females" (*Zen-Kousei* [Organ of Trade Union of Workers of the Ministry of Health and Welfare], 5 September 1993, in Japanese). Suppose that one of them would escape, mate with another common one and multiply. There is no evidence to refute our assumption that cockroaches in JNIH and the residential areas go in and out.

4.3.4 Besides the cockroach issue, JNIH has ignored our demand to give us the information not only about fleas, lice, flies and mosquitoes bred and researched in the laboratory of entomology, but also about them within the buildings of JNIH and other institutes. The fact is that there are many insects, as mentioned above, living with lab animals.

4.3.5 There are many homeless cats around JNIH. We were and are afraid that there would be the possibility that escaping lab animal(s) from JNIH would fell a prey to these cats. We asked JNIH to pay much attention to such a complex ecosystem involving vectors and host populations, including residents, around it. But JNIH has said that it has nothing to do with an EIS on the ecosystem.

4.4.1 The WHO manual reads: "Incineration is the method of choice for final disposal of contaminated waste, including carcasses of laboratory animals" (WHO, 1983, p. 21). It also reads: "*An incinerator should be readily available on site* or alternative arrangements should be made with the authorities concerned" (WHO, 1993, p. 29, emphasis added).

4.4.2 We understand that incineration is considered to be the best and safest method of disposing of infectious waste, and that therefore a laboratory should be set up at a site in a non-residential area where possible air pollution would not damage inhabitants. Such is the first and best alternative. The method of disposing after autoclaving is only an exceptional and insufficient alternative.

4.4.3 As a matter of fact, our mass media reported that most of the companies disposing infectious waste had neither their own incinerators nor licensed landfill sites. Infectious waste from

medical institutions, including the University of Tokyo Medical School, were reportedly often found scattered in valleys and/or fields. Therefore, we contended that it would be irresponsible for the JNIH to depend on such an *exceptional alternative.* It is a shame and to blame. *We contended that the JNIH should rather be a model to all other laboratories by adopting the best method of disposing of infectious waste.*

5. The informed consent by the concerned residents and public is a precondition

5.1 *It is our opinion that nowadays the principle of "informed consent" is one of the most important human rights and bioethics, and that this principle must also be applied to the promotion of public health and environmental protection in the age of emerging new pathogens and GMOs.*

5.2 Accordingly we were happy to be informed that Dr. Akira Oya, then Director of JNIH, himself agreed with this principle. In his letter of 14 November 1988 addressed to WU, he wrote:

"Nowadays there are many sites where laboratories of pathogenic microorganisms and/or life science are located in neighborhood of expanding residential areas in Japan. This implies that we are now in the age where the issues including biosafety of Level 3 laboratories and the attitude of these laboratories toward communities are to be questioned. *We are in the age where we have to give up a superiority complex of privileged scientists as well as a policy to leave all scientific researches unchecked. Contents and implications of scientific researches of laboratories should be*

checked in the light of safety of communities. Laboratories should be managed with understanding and cooperation of the residents of concerned communities. I think that needless to say, this principle should be applied to Toyama area, Shinjuku-ku, Tokyo. JNIH wants to manage its laboratory through consultation with the concerned people in this area" (emphasis added).

5.3 I am convinced that all of you and those who are concerned with the location issue of any biotech laboratory would fully agree with this declared principle of the JNIH.

6. It was the JNIH that changed its coat

6.1 For the first time, in February, 1987, I, on behalf of the residents, sent an open letter of questions to JNIH with the request that information be furnished about concrete conditions of the so-called "safety" of JNIH in such a densely populated residential area. My questions were written on the basis of the above theses contended by the WHO manual as well as the leading staff of JNIH themselves. To our surprise, their first reply was so poor that it had no information in reply to my questions. It seemed as if it were an examination paper written by a backward student. I could not but send my second open letter of questions to JNIH. Again, I was disappointed by JNIH's second reply, which led to my third open letter of questions to JNIH.

6.2. Those who are going to convince us of the "safety" of JNIH in such a site have to submit us the information about the probability of accidents caused by human errors. But JNIH could not do so. In this context, an excellent mathematician, one of the residents, has

proved by computer that the probability of accidents caused by human errors of about 300 researchers (excluding visiting and part-time researchers as well as students) at JNIH would be almost 100.00% every year. The leading staff of JNIH could not refute our thesis.

6.3 From February 1987 through November 1988, I and my colleagues, including the above mentioned mathematician, sent 14 open letters of questions to JNIH, but received only four very poor letters of reply. WU also sent five letters of questions to JNIH, but received four very poor replies.

6.4 The 14 open letters of questions we sent to JNIH and a few letters of reply from JNIH, together with many related documents, were incorporated into the two books entitled *How to Defend the Right to Life: For Human Rights in the Age of Biotechnology* (1988), and *Polemics: Toward Prevention of Biohazards* (1990a, all in Japanese), edited by myself. So, the issues of the polemics between us and JNIH have been made available to the public and scientific community. JNIH, however, could neither refute our theses nor publish even a scientific paper, not to speak of a book. *JNIH has already lost the case in the court of science.*

6.5 We repeatedly asked the leading staff of JNIH to reply to our questions and to continue dialogue between themselves and us. *We said we would be ready to give up our opposition to the location of JNIH in such a site, if they could prove scientifically our stance unfounded.* But JNIH took a strong stand against us, residents, handicapped people and WU, virtually stating "Shut your mouth!"

6.6 Meanwhile, the Mayor and the City Assembly of Shinjuku-ku (ward) with the population of about 270,000, unanimously supported

by all parties including Liberal-Democrats, Social Democrats and Communists, continued to urge JNIH to refrain from constructing the laboratory which was supposed to be undertaken under the protection of the police force.

6.7 *Only in one month later after Director Oya had sent his letter to WU (cited in 5.2 above), JNIH belied their own declared principle and public promise. Their last reply was "Shut your mouth!" On 13 December 1987, in defiance of strong protests from the side of residents, handicapped people, students and the staff of WU and the City Assembly, JNIH mobilized riot police of over 300 to attack us, residents and students of WU and arrested 30 students. Only backed by force, could JNIH start to construct its laboratory.*

6.8 What kind of attitude should we take to the JNIH in the face of such arrogance and negligence? Should we accept the fait accompli forced on us by the JNIH? Should we take a weak or soft attitude to the JNIH and approve their present location and the enforcement of their experiments? If so, should we breathe the exhaust from the laboratory?

7. Why the JNIH is on trial

7.1 Allow me to say some words about my theory of human rights. I learned very much about the theory of democratic human rights from John Locke, Thomas Jefferson and Thomas Paine. For the first time in Japan I translated the draft and final text of "The Declaration of Independence" of 1776 into Japanese and wrote many books and papers on the American Revolution and its implications for our times as well as the necessity of a new theory of civil and

human rights in the nuclear and biotechnological age. My paper on the new theory of human rights, which proposed to revive Locke's and Jefferson's theory of the right to resistance in all countries, including the so-called "Socialist" countries, in our times, was published in English in one of the most prestigious international journals (Shibata, 1977) and in German (Shibata, 1987) with international repercussions. Several scholars of international reputation, including Professors C.B. Macpherson and A. Rapoport at the University of Toronto, as well as Professor S. Brucan at the University of Bucharest, who later lead the people's revolt against Ceausescu, supported my new theory of human rights, while one of the leading philosophers of law in the GDR (East Germany) criticized mine.

7.2 On the other hand, the crude nature of JNIH, as heirs to the tradition of medical scientists of the biological warfare program of the Imperial Japanese Army (see 10.2 below and Shibata, 1990b, 1997a and 1997c as well as Harris, 1995), betrayed itself by mobilizing the riot police and suppressing the residents and students.

7.3 As a scholar of the theory of human rights, to fight for human rights, or not to fight: it was the question for me. It is in this context that I, together with many colleagues and residents, brought a lawsuit against JNIH seeking to have its transfer to our neighborhood as well as its location and experiments in this area halted.

7.4 In Japan there have been many lawsuits against chemical and pharmaceutical companies as well as the government, demanding for compensation for the lives lost or the damage to health caused by pollution and negligence. *In almost all cases, the victims and their*

families were too late to find their rights to life and health infringed. Only after hard lawsuits which usually extended over twenty years, some of their bereaved could receive only poor compensation. But it meant nothing to them when the lives of their family members were lost. Therefore, we do not ask JNIH and the government for any compensation. We ask only to have its dangerous experiments in so densely populated residential area halted.

7.5 Please be also informed that in Japan those who dare to bring a suit against the government have to be ready to be pressured by it, bureaucrats, employers and conservative circles. In this respect, only those who have courage to file a suit against the authorities and an insight in possible danger of emerging new pathogens and GMOs joined our group of the plaintiffs. I am proud of the unselfishness of all plaintiffs who have such courage and insight.

7.6 Since then, the public here have considered our lawsuit as one of the most important campaigns *not only for the environmental protection but also for democratic due process and human rights.* Almost all articles published in the mass media and many journals have supported us and criticized JNIH. *JNIH has already lost the case in the court of public opinion, as well.*

7.7 *If for many years to come there is any smallest possible risk of latent infection, cancer, bad smell, air and water pollution by exhaust air and drainage as well as risk of human errors, escaping lab animal, explosion, fire, earthquake and so on for residents, handicapped people, the staff and students of WU as well as patients in a neighboring hospital, all experiments of pathogens and GMOs at JNIH must be halted. This is the issue examined at the*

court.

8. The location issue of the JNIH in the light of the international regulations

8.1 When we started the campaign against the wrong location of the JNIH, we only asked the JNIH to respect the pioneering environmental law of the USA, that is, the "National Environmental Policy Act" of 1970 (NEPA).

8.2 In the last half of the 1970s the civil rights campaigns asking regulations against laboratories of GMOs developed in the United States. In 1977 the municipal ordinance for prevention of biohazards was issued in Cambridge, MA. Thereby the biohazard committee was set up to regulate the concerned laboratories. The same kinds of ordinance were issued in the States of New York and Maryland as well as several cities including Waltham and Amherst, MA, Princeton, NJ, and Berkley, CA. In 1981 the regulations by the ordinance of Cambridge were made more strict. The biohazard committee of the city was authorized to examine and approve the plan of biotech experiments of Level 2 and 3 as well as to inspect the concerned laboratories. In the same year the regulations of the ordinance of Boston, MA, were also made more rigid. (As to the ordinances and the debates on the environmental issue of biotechnology in the 1970-80s , see Lappe, 1984, Mantegazzini, 1986, Strauss, 1987, Fowle III, 1987 and Gibbs, 1987.)

8.3 To my knowledge, in the USA, since around 1982 the civil rights campaigns for regulation of biotech laboratories entered the new stage. Mr. Jeremy Rifkin filed several suits against biotech experiments and won the cases. In 1985 the residents of San

Francisco filed suit against the location of a Level 2 laboratory of the University of California San Francisco in the residential area and won the case, because the UCSF did not submit an EIS to the court. Since then, it has become required that a new biotech laboratory to be built at any site has to make public a prior EIS and risk assessment in order to obtain public acceptance. Without publication of an EIS, the UCSF could not set up its Level 2 laboratory at Laurel Heights in the city. The Department of Army (DOA) also had to make public the EIS of its Life Science Test Facility (LSTF) with a Level 4 laboratory, later downgraded to Level 3 laboratories in the Dugway Proving Ground. The DOA wanted to set up them in the Utah Desert, 90 miles away from Salt Lake City. The public opposition to the LSTF and Mr. Rifkin's lawsuit against its construction attracted our attention. In the USA, even a Level 3 laboratory in the desert had to submit its EIS to the public.

8.4.1 As to the civil rights campaigns against biotech laboratories in Japan, in 1981 the JNIH secretly constructed a Level 4 laboratory and several Level 3 laboratories at the site of its Branch in Musashi-murayama City in a suburb of Tokyo, without a previous announcement to the public, the consent of the residents as well as the Mayor and the City Council of the city. It is located in the residential area, although it is less populated than Toyama, Shinjuku-ku at the center of Tokyo. Therefore, immediately after the construction, the Mayor and the City Council, backed by the civil rights campaign there, asked JNIH to have the Level 4 laboratory closed, and protested against the constructed Level 3 laboratories. As a result, the JNIH as well as the Minister of

Health and Welfare could not but accept their demand. Since then, JNIH has publicly announced that no experiment has been done in the Level 4 laboratory. But it has ignored the protest against the Level 3 laboratories.

8.4.2 In this context, we later contended that the degree of containment of a level 4 laboratory was tighter than the Level 3 and 2 laboratories in Toyama, while Toyama is much more populated than Musashi-murayama City. Therefore, we insisted that it was paradoxical that NIID did not use the Level 4 laboratory in the less populated Musashi-murayama, while dared to use seven Level 3 laboratories and one big Level 3 animal facility in the most populated Toyama area.

8.5 In connection with the possible danger from the so-called physical containment laboratory, an American excellent science journalist, R. Hutton referred to A.G. Wedum's report (January, 1976) on the biosafety in the Level 4 laboratory of the US Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, MD. According to the report, 423 cases of laboratory-acquired infections occurred for the past 25 years (Hutton, 1978).

8.6 In 1988 in the USA the problems of the danger of biohazards originating from biotech laboratories and their impact on the residential area and environment again became one of the important environmental and political issues. The dangerous and poor safety conditions in the USAMRIID and the Yale University Medical School were disclosed and debated before a subcommittee of the Senate and the public (US Senate, 1988).

8.7 In 1989 the *Patriot-News*, a local daily of Harrisburg, PA, published a series of an excellent report entitled "Germ Wars" in its

25-28 June issues. It disclosed not only the biological warfare (BW) crime of the Imperial Japanese Army during the period of invasion of China as well as the American cover-up in the post-war period (Williams & Wallace, 1989 and Harris, 1994), but also the recent BW researches and human experiments on American citizens by the USAMRIID and other Army's facilities, as well as their impact on environment including residential areas as well as the danger of biohazards from them. The report was shocking especially to the citizens of Harrisburg. It motivated U.S. Rep. George W. Gekas, R-Harrisburg, PA to ask a bill to make the information on microorganisms treated in the biological defense laboratories available to the public. He said, "Those who protect our communities have a right to know" (The *Patriot-News,* 21 November 1989).

8.8.1 *The year of 1990 was a turning point* in the history of international regulations against biotech laboratories. On 23 April, 1990, the Council of EC issued "The Directive on the Contained Use of Genetically Modified Micro-organisms." Confirming that the precise nature and scale of risks associated with the contained use of GMOs are not yet fully known, it directs the member states to obligate their labs of GMOs to carry out *a prior assessment of the risk of the contained use for human health and the environment and to consult with the public about planned constructions and experiments.* It also obligates the labs *to take appropriate measures to inform any person liable to be affected by an accident on all matters relating to safety.*

8.8.2 In July of the same year the "Genetic Engineering Law" (GEL) took effect in Germany. According to it the Land authorities

license laboratories. *They can also enforce measures and carry out inspections on them.* They can seek advice from the Central Commission for Biological Safety (ZKBS), a panel of scientific experts, trade unionists, research council officials and others based in the Federal Health Office. Of course the GEL has some limitations from the standpoint of residents and people. It is not so highly evaluated by Germans who are critical of its loose regulations. I fully understand and support their disagreement. But in any case there are some legal regulations on labs of GMOs in Germany. It is also noteworthy that in 1993 a miscreant gene lab of the University of Marburg was inspected and ordered to be closed by the authorities under the GEL.

8.8.3 In the USA, the above mentioned Rep. G.W. Gekas did a good work to amend the law to regulate laboratories of pathogens and GMs. On 5 November 1990, Chapter 139 of title 10, the United States Code was amended by inserting the section 2370. Thereby almost all major laboratories, including the Centers for Disease Control (CDC), under the Biological Defense Research Program contract with the Department of Defense (DOD), have to submit to the Congress through the DOD, an annual report on research, development, test, and evaluation conducted by them during the preceding fiscal year. Each report should contain the following information: a description of all biological agents and their biological properties, a statement of the location of each research facility and the biosafety level as well as the documentation of annual coordination with local health, fire, and police officials for the provision of emergency support services. In the USA, public release of such information is now considered one of the most essential

preconditions for the promotion of public health.

8.9.1 As to the development of the civil rights campaigns against laboratories of pathogens and GOMs in Japan, in 1982, ignoring the opposition of the residents, RIKEN, that is, the semi-governmental Institute of Physical and Chemical Research (IPCR) set up a Level 4 laboratory at a less-populated site in the Science City of Tsukuba, about 80 km north-east of Tokyo, backed by the riot police. At that time, the IPCR could not but openly promise the public that it would refrain from dealing with live pathogens in order to prevent any biohazards. For the past 16 years since its construction the IPCR has performed only one experiment on gene of cancer in the controversial Level 4 laboratory. The IPCR is financed by the Science and Technology Agency and has nothing to do with pathogens.

8.9.2 Our campaigns against the wrong location of JNIH started in January 1987. It motivated many residents throughout Japan to pay much attention to the location issue of laboratories of biotechnology. As a result, Cities of Osaka and Suita near Osaka signed an agreement with the residents of Suita that the both cities would never deal with Level 3 pathogens at the two new biotech laboratories located in residential areas in Suita. The same kind of regulations, which ban any experiments dealing with Level 3 pathogenic microorganisms in residential areas, were agreed between laboratories and concerned residents in a number of cities in this country.

8.9.3 On 5 March of 1990, even the Environment Agency (EA) of Japanese government officially confirmed that procedures on the prior assessment of a new location for a biotech lab as well as due

process of residents' informed consent and agreement are not yet clarified. At the same time, the EA made public the list of members of the newly organized "Committee for Environmental Protection of Biotech Labs" to study the procedures. The intention was appreciated, but all its members, including a leading expert of the JNIH, were those who wanted to ignore the necessity of regulations on biotech labs. Since its set-up no business has been done. The EA seems to have acted merely for show, as if it were interested in international environmental regulations on biotech labs.

8.10.1 In the successive years we could observe *the further development of the international trend to regulate laboratories of pathogens and GMs*. Following the "Directive" of the EC, the UK enforced a new law "The Genetically Modified Organisms (Contained Use) Regulations 1992." This was a new step toward promotion of public health in the age of emerging new pathogens and biotechnology. In February 1994 it was reported that the Health and Safety Executive (HSE) as an independent governmental inspection agency, applying the new regulations for the first time, ordered a ban on gene experiments at Birmingham University. This was one of the most remarkable events in the history of efforts for prevention of biohazards. (See, *The Independent,* 4 Feb., *The Times,* 5 Feb., *Nature,* 10 Feb. and *New Scientist,* 12 Feb. of 1994.)

According to a report on the ban on the experiments at Birmingham University, "The inspector found that the safety cabinets were in an ordinary laboratory, with other researchers working alongside those experimenting with the modified viruses. Cleaners and other staff had access to the area and corridors connected it to administrative offices. There was no way to seal off the laboratory in case of an

accident. He concluded that the standard of containment fell a long way short even of level two" (Bown, 1994). This description is just applicable to the JNIH, too. Therefore, if we should apply the same principle to most of the level 2 laboratories at JNIH, they should be ordered to be closed immediately.

8.10.2 In 1993, WHO published a revised 2nd edition of the *Laboratory Biosafety Manual*, under editorship of Dr. C.H. Collins. Compared with its 1st edition of 1983, the regulations became more strict toward prevention of biological, chemical and radioactive hazards. Of course, as the title shows, it deals mainly with the biosafety conditions within the laboratory. But it is noteworthy that it also paid more severe attention to the environmental protection. Most of the words "should" in the 1st edition were replaced with the words "must."

8.11.1 We were shocked at an article written by S. Leskov, a reporter of the *Izvestia* according to which an explosion occurred at the duct of an institute of veterinary science in Moscow. As a result, aerosols of *brucella* reached the neighboring college where many students were infected with *brucella* and 15 of them died. Hereafter, such laboratories were reportedly transferred from Moscow to non-residential areas. (The Asahi's Weekly *AERA*, 20 February 1992, in Japanese. The date of the accident was not reported. Neither English nor Russian text was available.)

8.11.2 We were further shocked to read the terrible report on the Sverdlovsk anthrax outbreak (Meselson, et al., 1994). In this biohazard 68 citizens died by the aerosols of *Bacillus anthracis*. From these tragedies of biohazard we learned three lessons. Firstly, it is evident that these cases of the outbreak were confirmed by the

fact that so many students and residents suddenly infected with deadly pathogens and died. If they were latently infected with non-deadly or opportunistic pathogens and/or carcinogens by aerosols from laboratories, the outbreaks of them would never be recognized. Secondly, no body can recognize the whereabouts of aerosols. Therefore, no aerosols should be discharged in residential areas. Thirdly, the JNIH discharging aerosols must not be located in the present area.

8.12.1 In September of 1993, an editorial of the weekly *Nature* warned the public of an accident in the Arborirus laboratory at Yale University. It reported that a scientist there was spattered with deadly Sabia virus when a test tube broke in a high containment laboratory. He failed to report this accident to university authorities and took a trip exposing the virus to friends. The accident was not discovered by the authorities until the researcher became ill. This means that an accident could occur even in a high containment laboratory, that deadly virus could escape therefrom by researchers themselves, and that the risk management is most decisive in preventing spread of pathogens from laboratories. Thus the editorial states: "Who would want to live in the vicinity of a laboratory that houses dangerous viruses if the scientists cannot be trusted to follow the strict rules of containment that they themselves have laid out?" The editorial further proposes that public health officials had to at least threaten to close such a laboratory (*Nature*'s editorial, 1994).

We can further add some documents about the accidents in containment laboratories (Morgan, 1987, Weiss, et al., 1988, Barnes, 1988, CDC, 1988, Khabbaz, et al., 1994).

8.12.2 In 1993 and 1994, two important books appeared to warn the public of danger of laboratories of pathogens and GMOs. R.M. Hening, an American science journalist, assisted by several leading scientists of pathogens and GMOs, disclosed that there were possibilities that pathogenic microorganisms surely escaped from some laboratories in the world and infected residents and public (Hening, 1993). Another warning came from R. Preston's excellent reportage on not only the Ebola outbreak in Zaire but also a possibility of its outbreak in the USA (Preston, 1994). The Japanese version of it was one of the best sellers in 1995 in Japan. These books appealed the public to pay much attention to the necessity of the regulations against the safety and environmental conditions of the laboratories.

8.13 Recent achievements in the science and laws of the environment, including the "Civil Amenities Act" [CAA] of the UK, further dictate to human communities to respect human rights to amenity, in addition to human rights to life and safety. According to the CAA of the UK, "amenity" is defined as "the right thing in the right place." Except the leading staff of JNIH, nobody dares to contend that laboratories dealing with deadly pathogens, carcinogenic chemicals and radioisotopes, lab animals and infectious waste is "the right thing" in most populated residential areas.

8.14 We have fully agreed with these international regulations and warnings and only asked to apply them to the JNIH issue. I am ashamed that in the light of international regulations against laboratories of pathogens and GMOs, especially in contrast to the UK, Japan is the most unregulated and backward country in the world. If we had had regulations such as those of the UK, we could

immediately have closed JNIH because of such poor risk management and such unsuitable location and environmental conditions. Also, in contrast to the spirit of environmental law and its legal procedure in the USA, JNIH has haughtily refused our demand to be informed of its EIS and risk assessment as well as to reply to the questions raised by us. As a result we had to file the suit against it.

9 . What has been confirmed and proved at the court for the past nine years?

9.1 In September of 1992, lawsuit was still in dispute. Nevertheless, JNIH moved to a new laboratory constructed at the new site without the agreement of residents and WU, as well as the Mayor and City Assembly of Shinjuku-ku. It is a cursed site, where the biological warfare (BW) headquarters of the Imperial Japanese Army was located during the period from 1932 through 1945 when Japan occupied China. It was called the re-location at the old haunt of the BW medical scientists. Since then, it turned out that some theses presented by us about the environmental disturbance and possible hazards were correct.

9.2 For the past six years since then there has often been a bad smell around JNIH. Residents, handicapped people and professors of WU often claimed that the air from JNIH smelt of formalin.

9.3.1 On 23 July 1993, a dead rat was found on the premises of JNIH. On 5 November 1993 a live mouse was found at the waste storage site outside of the animal facility. These facts were confirmed by JNIH. One day some residents reported me that they

had seen children playing with white mice which may be one of some unidentified escaping lab animals from JNIH.

9.3.2 At 8.48 am on 31 July 1995 a hamster-like lab animal was seen passing from JNIH laboratory through a side entrance gate of JNIH to the street by three sitting-in residents, including myself. We immediately asked Director Shudo Yamazaki to meet us and explain the accident to us, but he refused to do so.

9.4 In 1992-93, Dr. Shigeo Honjo, Honorary Fellow of JNIH and Professor of Aichi University, appeared three times as a witness on behalf of the plaintiffs before the court. He, as an expert of veterinary science, was a director of the Tsukuba Primate Center, JNIH, until he retired from JNIH. The TPC is located at a vast non-residential site in Science City of Tsukuba. In the 1960s the government decided to move all governmental institutes, including JNIH, from Tokyo to Tsukuba, but only two of them, that is, JNIH and the National Institute of Nutrition (NIN) refused to accept the decision on the pretext of "inconvenience of communication." Instead, JNIH set up only the TPC there. Such was the origin of the controversial location issue of JNIH. Dr. Honjo said that laboratories such as JNIH should be located at such a site. He also testified on the structural defects, including the narrowness as well as the shortage of the space for assisting experiments, of the animal facility at the laboratory in Toyama. When a representative of the defendant cross-examined Dr. Honjo, even the former himself, admitting such defect, could not but ask, "Why don't you understand our policy that such defects of the laboratory should be supplemented by the risk management of the staff?" It provoked a boisterous laughter of hearers at the court.

9.5.1 In 1993-94, Dr. Hideo Arai, Senior Researcher at Department of Bacteriology, JNIH, as a witness for the plaintiffs, testified three times on the dangerous conditions of JNIH at the court. He caught over 100 cockroaches in a few weeks in his room and laboratory and showed them to the judges at the court. It was shocking. As a result, it motivated the leading staff of JNIH reluctantly to make an arthropod control program. Nevertheless, JNIH has not been able to exterminate cockroaches. According to a report submitted by the arthropod control company which is under contract with JNIH and re-submitted to the court by JNIH, 1,538 cockroaches were still caught during the period from April 1995 to March 1996. This means there are still numerous cockroaches in JNIH. As a matter of fact, Drs. T. Kitamura and S. Yamazaki, as witnesses for JNIH, confessed at the court that it would be impossible for them to exterminate cockroaches there.

9.5.2 Dr. Arai further testified that for the past eleven years from 1982 to 1993, twelve JNIH researchers died. Among them, two died soon after retiring. Ten of the total number died from cancer while one of the two others died from cirrhosis of the liver. Four of them were in their 60s, four others in their 50s and one each in their 40s and 30s. Among the carcinogens regularly handled by researchers are radioisotopes and various organic solvents. Dr. Arai said: "Organic solvents and genetically mutated substances regularly became aerosolized and released into the air, when they were used as liquids." So, the researchers could not but breathe the carcinogenic aerosol. As a result, maybe they had cancer and died. His testimony reminded us of the report in 1986 over the deaths of former researchers at the Pasteur Institute in France. It turned out that

JNIH was another Pasteur Institute in Japan. This suggests that the residents around it are also forced to breathe such aerosol in many years to come. The testimony received a big coverage in the Daily *Mainichi Shimbun* in Japanese and English. The article in English (*Mainichi Daily News,* 19 January 1994) was entitled "Trial begins over cancer deaths at health institute."

9.6.1 The JNIH said that the newly built laboratory was completely "safe" because it was built in accordance with the international regulations including the WHO manual. It also insisted that all experiments would be done and controlled in accordance with these regulations. Therefore, JNIH submitted the Japanese translation of the first edition of the WHO manual to the court. The translation, however, includes a number of words mistranslated, apparently in purpose. It further referred to and cited its second edition. Later, it submitted the Japanese translation of the second edition to the court. Again the translation includes many words mistranslated apparently intentionally.

9.6.2 Learning that the new edition of the WHO manual was available, I purchased a copy. Drs. Arai, Honjo and several other concerned researchers of JNIH assisted us in checking the biosafety conditions of the new laboratory in the light of the WHO manual. To our surprise, it turned out that the new laboratory and biosafety management were full of defects, and that the laboratory had been built and was being managed not in accordance with what JNIH called "international regulations." Allow me to mention some of the defects as follows:

9.6.2.1 As to some of the structural defects of the basic laboratories (Level 1 and 2), ceilings and most parts of walls are

not impermeable to liquids; bench tops are not sealed to the walls; open spaces between and under benches, cabinets and equipment are not easily accessible for cleaning; there are no hand-wash basins near the door; doors have no appropriate fire ratings; there are neither emergency shower nor eyewash facilities, bad and poor sites of biological safety cabinets should be rectified, and so on. Most of the Level 2 laboratories are the large rooms where many researchers deal with different kinds of pathogens. So, someone comes in and goes out when work is in progress. One of the most important principles of biosafety is: "One pathogen in one closed room at one time." But this principle cannot be applied to most of Level 2 laboratories.

9.6.2.2 The Level 3 laboratories may seem to be "new" and "clean" to visitor's eyes. With regard to these laboratories, we found not so many faults except four important ones. Firstly, so many laboratories (seven Level 3 laboratories and a Level 3 animal facility with the same area) are densely concentrated at one of the most populated residential areas in Tokyo. Secondly, all of them are located in the basement where the rooms of boilers, incinerator and many machines are located, too. There is the danger of explosion and/or fire. It would not be easy for researchers in these laboratories to evacuate in case of emergency, fire and/or earthquake. Thirdly, the regulation of the two-person rule (WHO, 1993, p. 19) is ignored, because there is only one researcher in each of some fields of Level 3 pathogens. Fourthly, the heavy devices would be thrown down in case of a heavy earthquake like the Kobe Earthquake, because they are not fixed to wall and floor. In this case, it would be difficult for researchers to evacuate out of the

laboratories.

9.7 The WHO manual is mainly concerned with the biosafety *within* laboratories, not with their environmental and ecological conditions. What we are concerned is mainly with the latter. Even if JNIH completely observes the minimum standards recommended by WHO, we do not think that a so densely populated residential area such as ours is a proper site of JNIH in the light of the international regulations on the necessity of an EIS and the public informed consent formulated by the "NEPA" of the USA as well as the "EC Directive on the Contained Use" (see, 8 above).

9.8.1 In 1994-95 Dr. Kitamura appeared four times at the court as a witness for JNIH. We submitted a lengthy list of defects which we made as a result of our checking of the laboratory, the devices used, and the safety management. He was cross-examined by us and could not but admit that he was ignorant of the concrete recommendations in the first and second editions of the WHO manual. He could not refute our list and said that the regulations of the second edition were too strict and minute to be observed at laboratories of pathogens and GMOs, and testified that his colleagues not only in Japan but also in other countries had sent many letters of disagreement to WHO.

9.8.2 I immediately doubted the honesty of Dr. Kitamura, because I had already publicly proved that his "prestigious" paper (Kitamura, 1984) was only a piece of plagiarism, and that JNIH was an unscientific and shameful institute which advocated plagiarism. His testimony prompted me to send a letter of 15 August 1995 to Dr. Grist who wrote a preface to the second edition of the WHO manual, asking for information. On behalf of him, Dr. Collins

replied to me. As was expected, the reply from Dr. Collins suggested that Kitamura was incorrect. It was in this context that Dr. Collins, in his "Statement" of 22 October 1996 submitted to the court, wrote: "No adverse comments of any substance were received in respect of the second edition" (Collins, 1996).

9.9.1 Since the Kitamura's testimony, the leading staff of JNIH changed their tactics. They sent letters to their WHO and CDC colleagues and asked for their replies to the effect that it was up to each member states to decide on the implementation of the recommendations by WHO. Thus, the letters from Dr. L.J. Martinez, WHO (2 November 1995), Mr. V.R. Oviatt (8 November 1995), Dr. C.J. Peters, CDC (8 November 1995), and Dr. J.Y. Richmond, CDC (9 November 1995) were submitted to the court. *We are sorry that these WHO and CDC scientists have been used purposefully for propaganda and sabotage by the JNIH* as if it were qualified to arbitrarily interpret and ignore the minimum set of guidelines for biosafety and environmental protection in the WHO manual.

9.9.2 I fully agree with the thesis confirmed by the above scientists referred to in 9.9.1 and Dr. Collins which is: "it is up to *each member state* to decide on the implementation of these recommendations" (Collins, 1996, emphasis added). Please note that "each member *state*" means the parliament and government, not an individual institute like JNIH. In Japan there is no law providing to qualify JNIH for the implementation of the recommendations described in the WHO manual and other international regulations including the EC "Directive on the Genetically Modified Organisms (Contained Use)" (1990). Dr. Kitamura himself was often proud

that he had been invited to the WHO meeting in preparation of the WHO manual (first edition), but never urged the concerned ministries, including the Ministry of Health and Welfare (MHW), the Environment Agency (EA) and the Science & Technology Agency, to submit a draft law on the implementation of the WHO manual to the Diet.

9.10.1 *Thus, Japan is an unregulated country in respect to research of pathogens and GMOs.* For example, the WHO manual directs: "Laboratory in this category (Level 3) should be registered or listed with the national or other appropriate health authorities" (WHO, 1993, p. 19). Further it reads: "A written contingency plan for dealing with laboratory accidents is a necessity in any facility that works with or stores Risk Group 3" (ibid., p. 55). One of the items which should be included in the plan is "identification of at-risk personnel and *populations*" (emphasis added).

9.10.2 But there is still no law providing for implementation of these regulations. There is no law in Japan to designate JNIH as an institute with obligations to implement the WHO manual. In this country there is no independent inspection agency like the HSE in the UK.

9.10.3 Under the circumstances as such, all laboratories of pathogens, GMOs, lab animals and cancer-causing chemicals do not have to obtain any permission from any governmental agency. All of them are neither registered, nor inspected and controlled by any agency. In addition, there is neither law nor regulation to obligate them to make the information about the risks of their activities available to the public, including local residents and communities. *As far as the international standards of regulations on risk*

assessment and EIS of laboratories of pathogens and GMOs are concerned, Japan is an anarchical country.

9.10.4 It is in this context that the Aum Cult, the fanatic and criminal sect of Japan, could freely set up a laboratory in a populated residential area for the terrorist purpose of biological warfare against citizens. It was confirmed at the Tokyo District Court that since 1991 the Aum Cult had massively cultured *Bacillus anthracis* and *Clostridium botulinum* and scattered the aerosols of the former in the residential area in 1993 and of the latter in a subway station in 1995 in Tokyo. Fortunately the cult failed to kill citizens, although it succeeded to kill many citizens with the deadly toxic gas, Sarin. Nevertheless, there is still no legislation to subject the Aum Cult to penalty in this case. *In this respect JNIH is to blame, because it not only has done nothing to make the* WHO manual *known to the concerned ministries and the public, but also has done the utmost to resist enforcement of it in Japan. It is a shame.*

9.11.1 The Kobe Earthquake on 17 January 1995 was one of the most serious disasters in the postwar Japan. As you maybe know well, many houses and buildings were destroyed and burnt out. About 6,500 citizens died directly and indirectly by that earthquake.

9.11.2 *Here I would like to invite your attention to another element which has been ignored in the hitherto accepted biosafety guidelines and manuals.* The earthquake occurred early in the morning, when all laboratories there were closed. Almost all bottles of chemicals were broken in most of the laboratories there, and explosion and fire occurred in several laboratories. The electric current and water were cut off. Most of refrigerators, freezers, culture stirrers,

shakers, agitators, safety cabinets and other equipment were knocked down. Water pipes under the floor were cut. Even ducts and walls of Level 3 laboratories were destroyed or cracked. It is assumed that pathogens and their aerosols must be scattered in many laboratories and the environs. In addition, staff in the laboratories could not identify the exact parts and conditions of the broken water pipes. As a result, the floor was later flooded when water supply was recovered. A number of lab animals reportedly escaped.

9.11.3 In this connection I remember the Sendai Earthquake of 12 June 1978. It was later reported in *Journal Laboratory Animal* (4(3), 1987, in Japanese) that the animal facility of the Medical School, Tohoku University, Sendai City, was destroyed by the earthquake, and that as a result 977 lab animals escaped therefrom. (Sendai is a big city with one million population.)

9.11.4.1 In this connection, please be informed that the campus of WU and the public park adjacent to west site of JNIH are the legally designated sites of refugees in emergency of a big earthquake and/or fire. In such an emergency, it is expected that tens of thousands of residents will seek refugee from an earthquake and/or fire. The JNIH-NIID is located just at the center of these sites.

9.11.4.2 You are asked to suppose that an earthquake of a magnitude such as the Kobe and Sendai earthquakes occurred in the daytime when laboratories like the JNIH-NIID are full of staff doing experiments with large quantities of pathogens, GMOs, chemicals and other hazardous material. What about the risk of outbreak of pathogens which would surely be caused by numerous escaping lab animals? How about the risk of outbreak of them

among tens of thousands of refugees in the devastated and unsanitary cities without water supply, when an earthquake should have occurred during the summer? In cities devastated by the earthquake there must be a large swarms of insects including flies and cockroaches, as well as a large number of rats and mice as vectors of pathogens especially in the summer. *In the light of the experience of the Kobe and Sendai earthquakes, we contend that there should not be any laboratories of pathogens and GMOs located in residential areas. This is one of the most important and serious lessons we learned from the recent earthquakes.*

9.11.4.3 Japan is a country of many earthquakes. In this respect, the regulations on the contingency plans and emergency procedures (WHO, 1993, pp. 55-59) are not enough as procedures against danger of earthquakes as well as explosions and fires caused by them in laboratories located in residential areas. But, even the regulations of the WHO manual have been ignored by JNIH.

9.12.1 In 1996-97 Director Yamazaki of JNIH as a second witness of the defendant appeared four times at the court. In contrast to Dr. Kitamura, this time Director Yamazaki testified that he could find nothing which violated the regulations recommended in the WHO manual. Thus he negated Kitamura's testimony to the effect that the WHO manual was too much strict and minute (see 9.8.1). In face of our cross-examination, however, he could not but betray himself by admitting that he was ignorant not only of the details of the regulations in the WHO manual but also of the concrete defect conditions of the laboratories, devices and risk management in JNIH.

9.12.2 It turned out that he was also ignorant of the well-known

international and national regulations mentioned in 8 above. He also testified that any EIS or risk assessment of laboratories of pathogens and GMOs was scientifically impossible and no assessment was made public in any countries. Such a perjury was immediately refuted by us, because at the court we showed the original versions of the EISs on the Level 3 laboratory in the Utah Desert, Utah as well as on the Level 2 laboratory of the UCSF, San Francisco, California.

9.12.3 The site of JNIH is located right at the center of the most populated residential area, where two social welfare facilities for handicapped people, many schools including WU, kindergartens and nursery schools are located. Therefore, WU and the International Medical Center of Japan (IMCJ, a major hospital in the neighborhood) refrained from using incinerators so that they might not add to air pollution. Only JNIH has continued to dare to use incinerator for disposal of garbage and paper. Director Yamazaki was also ignorant of the concern of WU and IMCJ in connection with air pollution. We asked him an EIS on carcinogenic elements, including dioxin, in the exhaust and smoke from JNIH. But he confessed that he did not order to have dioxin in the exhaust and smoke surveyed.

9.12.4 Recently it turned out that most of the children living at a tall housing complex near the JNIH had symptoms of asthma. These symptoms are suspected to be caused by the exhaust and smoke from JNIH. This fact was reported at the City Assembly of Shinjuku-ku. We asked Director Yamazaki to make public its EIS as soon as possible. However, he has refused to do so.

9.12.5 Through a series of testimonies and our cross-examination

Director Yamazaki betrayed himself that JNIH had no concerns about environmental protection. YOKEN, Japanese name of JNIH, literally means "National Institute of *Preventive* Health." As a matter of fact, JNIH has already played a role of *prevention* of health of residents, handicapped and immune-deficient people as well as students and staff of WU.

9.13.1 We, representatives of town communities and professors of WU have often provided the Mayor of Shinjuku-ku and the City Assembly with new information on the possible danger from JNIH and asked them to support us. They paid much attention to the polemics between us and JNIH at the court. As a result, they came to the conclusion that there was no evidence to prove the so-called "safety" of JNIH at the present site. The Deputy Mayor confirmed this to the residents including the representatives of the plaintiffs and the Faculty of Literature, WU.

9.13.2 On 17 December 1993 and 5 August 1994, the Mayor of Shinjuku-ku sent two documents demanding the Director of JNIH to observe four points. *These demands were unanimously supported and adopted as a resolution by the City Assembly on 30 September 1994. Both asked the Director of JNIH as follows*:

9.13.2.1 The meetings and the information of the so-called "Biosafety Committee" must be made public.

[Shibata's comment: JNIH set up this "Committee" in order to have the public think as if JNIH were open to the public. It comprises a vice-director of JNIH, a few manipulated residents and a few medical scientists patronized by JNIH. The Municipal Office of Shinjuku-ku was requested to send a few responsible officers as the members of the "Committee" by JNIH. But the Office refused

to obey the request. According to the Office, a few staff members attend only as "observers" for information. The "Committee" chaired by the vice-director meets in closed session. Except a few manipulated people, neither residents nor reporters of the mass media are allowed to attend and listen to its meetings. No information about the "Committee" has been made available to the public. *It is only a puppet "Biosafety Committee" of JNIH, by JNIH and for JNIH.* It is noteworthy that even the Mayor and the City Assembly asked JNIH to make the so-called "Biosafety Committee" open to the public.]

9.13.2.2 An ID tag must be attached to each of all lab animals. [Shibata's comment: This demand is reasonable not only from the viewpoint of the concerned residents but also from the viewpoint of the regulations of the governmental "Guideline of Modified DNA Experiments," according to which lab animals experimented with GMOs must be attached a special tag.]

9.13.2.3 The residents must be informed how to distinguish possible escaping lab animals and how to treat them.

9.13.2.4 JNIH is allowed to make its experiments only with the consent of the residents. Without their consent, JNIH must halt its experiments.

Since then, almost over four years have passed. But the demands of the Mayor and the City Assembly have remained ignored by the Director of JNIH.

9.14. On 28 February 1996 the wrong location issue of JNIH was discussed in the Environment Committee of the House of Councilors. *Minister Sukio Iwadare of the Environment Agency admitted that the location of JNIH was wrong, and said to the effect that JNIH*

should be moved to a non-residential area as soon as possible in the light of the lessons of the Kobe Earthquake.

9.15 As to the details of our lawsuit, our all documents (1989-1993) submitted to the court were incorporated into a book (Shibata, 1993b). It was published for information for the scientific and legal communities as well as the public. It is expensive but sells well, and I am going to edit the Volume II, into which the successive documents of the suit will be incorporated. So, I think, the public, including scientists and lawyers, are well informed of the deliberations of our suit. Since our filing of the suit, nine years have passed. As a matter of fact, very few favored the present location of JNIH in the mass media and journals. I am pleased with the fact that our suit has already been able to contribute something toward warning the public of the urgent tasks for prevention of biological, chemical and radioactive hazards which could originate from laboratories such as JNIH, and that our campaign has enjoyed an ever increasing support among the public (Hesse, 1991, 1992, 1997) here and abroad.

10. Why the JNIH could not but change its name? The misdeeds of the JNIH examined

10.1 You might perhaps wonder why the leading staff of the JNIH have so arrogantly dared to infringe on the human rights of the residents and the public. We think that one of the reasons could be found in the origin and history of the JNIH.

10.2.1 In 1932 the Imperial Japanese Army (IJA) set up the Laboratory of Infectious Disease Control (LIDC) at the Army's

Medical College in Toyama, Shinjuku-ku, Tokyo. This was the headquarters of Japan's biological warfare (BW) program. In the next year the IJA founded Unit 731, headed by Lt. Gen. Shiro Ishii in north-east China. During the period of the successive invasions of Asian and Pacific countries by the IJA the BW network expanded to comprise many units and sub-units from north-east China to Singapore as well as most of medical schools, including the Medical School and the Institute of Infections Diseases (IID) attached to the University of Tokyo, the Medical School of the University of Kyoto and the Medical School of Manchuria. The network conducted cruel human experiments in order to develop biological weapons. About 10,000 Chinese including women and children were reportedly killed as human guinea pigs throughout the network. I estimate that about 1,000 scientists, in the fields of medicine, veterinary science, entomology and so on, helped design these human experiments and made use of the results in BW operations against Chinese people (see, Williams and Wallace, 1989, Harris, 1994 and Gold, 1996).

10.2.2 After Japan's defeat in 1945 the network was disbanded, but the story did not end there. Ishii, his cohorts and leading BW doctors turned the network's secret medical records over to U.S. forces in exchange for immunity from war crimes charges. What became of the medical researchers and other scientists who collaborated with the BW program?

10.2.3 The JNIH was established in the campus of the IID on 21 May 1947 by the order of the U.S. authorities. It was staffed with former members or associates of the network including Unit 731, LIDC and IID. All of seven JNIH directors between 1947 and 1981, as well as most of the leading staff had belonged to the network.

Documents confirm that from 1947 to 1990, loyal to the tradition of the network, the JNIH scientists have conducted bacteriological experiments with pathogens and non-approved vaccines on babies, prisoners, patients in psychiatric hospitals and soldiers of the newly organized Defense Forces. For about 20 years since its foundation the JNIH continued to cooperate intimately with the U.S. Army 406th Medical Laboratory, a branch of Fort Detrick, which was located at Yokohama, Tokyo and lastly Sagamihara City near Tokyo. The JNIH scientists have often been offered financial aid from U.S. military institutions (Shibata, 1989).

From 1947 through 1975, JNIH also helped the Atomic Bomb Casualty Commission (ABCC) in Hiroshima and Nagasaki, a U.S. military facility which did not cure many atomic survivors but treated them only as human guinea pigs in order to get data about the atomic bombs' radioactive after-effects on humans (Lindee, 1994 and Shibata, 1996b).

We have also found that JNIH has been cooperating with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, the U.S. Army Walter Reed Institute of Research and other institutes, which have all played leading roles in the "Biological Defense Program" of the Pentagon.

10.2.4 In July 1989 construction workers on the JNIH site unearthed about 100 human skulls and thighbones that appeared to date from WWII. (See, "Skulls found: Japan doesn't want to know whose," *The New York Times*, 13 August 1990.) These were found on the former LIDC site, that is, the new site of JNIH. According to a scientific investigation, most of the skulls and bones are considered to be the remains of the victims killed by the BW network. *It is a*

chilling coincidence that JNIH selected the haunt of LIDC as its new site.

10.3.1 It is said that JNIH has screened the vaccines, antibiotics and other biological products, that it has carried out basic research into infectious diseases, and that it has thereby played a vital role in the control of them, much like the CDC in Atlanta, USA.

10.3.2 Has the JNIH really contributed toward promotion of public health in Japan? As the biggest institute of pathogens financed by the government, it is natural that the JNIH has contributed a little toward the control of infectious diseases, but we should not excuse its dark side. In fact it has done considerable damage in the name of disease control.

10.3.3 On 11 July 1983 *the criminal scandal at the JNIH was disclosed and then JNIH was searched by the police and one researcher was arrested on charges of improper screening of antibiotics.* Then he was sentenced to three-year imprisonment with a five-year stay of execution and the director had to resign his office from a sense of responsibility. At that time the mass media reported that such a crime was inevitable because of the "structural connection" between the JNIH and many pharmaceutical companies, that it was only the tip of the iceberg.

10.4.1 Here I would like to mention only two of many scandals. The first one is *the case of ineffective vaccination against influenza.*

10.4.2 Dr. Hideo Fukumi was a member of the LIDC at the end of WWII. He became the Head of the Department of Bacteriology at JNIH after the war and later its vice-director (1973-77) and director (1977-80). In 1957 he urged the MHW to set up a system of collective vaccination against influenza for all kindergartners and

schoolchildren. In 1962 the system was set up and the vaccination became compulsory. Thereby every year about 15 million children were compulsorily vaccinated against influenza. Of course this system brought much profit to pharmaceutical companies.

10.4.3 However in a few years it turned out that the vaccine was not only ineffective, but also risky. Many children became sick because of it and some of them died or suffered physical and/or mental handicaps. Their parents initiated a campaign against the compulsory vaccination and further filed a number of lawsuits against the government, especially the MHW and asked the state compensation for their damages.

10.4.4 In 1987 Dr. Kousei Takahashi, former Lecturer at the University of Tokyo Medical School, published a book (Takahashi, 1987). In this book he proved that Dr. Fukumi and the leading scientists at the JNIH had been aware of the ineffectiveness of the vaccination before the system was proposed and introduced, and that their methods were unscientific. Since then, no refutation against Dr. Takahashi has been written by leading staff of the JNIH.

10.4.5 A number of the lawsuits took above 20 years. At last, in 1992, a group of the victims and parents as the plaintiffs won the case against the government as the defendant. As a result, in 1993 the MHW decided to give up the compulsory system of vaccination against influenza and the Minister of Health and Welfare could not but apologize to many victims and the public for the fault of the system. However, no leading scientists of the JNIH have ever apologized to them for it.

10.4.6 A few years ago I checked the main papers on the "efficacy"

of influenza vaccine written by the JNIH experts. I found that all critical arguments submitted by Dr. Takahashi were almost affirmatively confirmed by them. Dr. Masato Tashiro, Head of the First Department of Virology, JNIH, openly confirmed that there was no scientific paper which proved the "efficacy" of it (*The Daily Industrial Paper*, in Japanese, 20 February 1997). Dr. Hideo Arai, Senior Researcher of JNIH, who is also critical of the "efficacy" of it, testifies that no members of JNIH dare to inject the influenza vaccine into bodies of themselves and their own families. Nevertheless, every winter the director and the experts of JNIH propagate to recommend the vaccine to the public. Why?

10.5.1 The second case is *the tragedy of hemophiliacs caused with the HIV-contaminated blood products which were screened and approved by JNIH.*

10.5.2 In the 16 July, 19 December 1982 and 4 March 1983 issues of the *MMWR*, a prestigious weekly, the CDC reported that three hemophiliacs had a disease of AIDS through the injection of unheated blood products, and three times warned the public of the possible AIDS risk of them. In the USA unheated blood products soon became unused. Then, American pharmaceutical companies rushed to dump their blood products on Japanese companies, including the Green Cross founded by former Lt. Colonel Ryoichi Naito of Unit 731, because these products continued to be approved by the JNIH. The information of the CDC had reached JNIH immediately. But the JNIH continued to screen the blood products in question and to affix the "Approved by NIH" stamps on them until 1985. In Japan only the JNIH is legally allowed to approve the blood products. Without the JNIH stamps no blood products are allowed

to be sold and used. *As a result about 2,000 hemophiliacs were infected with the HIV and over 450 of them have reportedly already died.*

10.5.3 From the beginning of the 1990s to 1996 the tragedy of the victimized hemophiliacs and their lawsuits against the government, especially the MHW, was one of the most controversial, political and social topics in the mass media. The mass media concentrated only to fix responsibility on a few bureaucrats of the MHW. Of course they are to blame for the sabotage, but the mass media did not even mention the responsibility of the JNIH as a governmental screening office and its role in spreading the *HIV* among hemophiliacs.

10.5.4.1 In March 1996 I made interviews with the leading staff of the JNIH who should be responsible for the wrong approval of the blood products in the period from July 1982 to December 1985. They included Drs. Akira Shishido and Shigeo Hayashi, then Directors, Dr. Jun'ichi Yasuda, then Head of Department of Blood Products, Dr. Yamazaki, then editor of a Japanese versions of the *MMWR*, and Dr. Kitamura, Head of the HIV Laboratory. All of them negatively replied to my questions and said that they had nothing to do with the responsibility in this case.

10.5.4.2 I did know that Dr. Yasuda had already in June 1983 been aware of the deadly effect of the unheated blood products, that he had nevertheless continued to approve them until December 1984, and that then in January 1985 he had been offered a lucrative post in Nihon Zouki, Inc., one of five major companies which profited greatly by selling many lots of the HIV-contaminated products with the JNIH label.

10.5.4.3 I also checked each volume of the *Yearbook of JNIH* in that period and found the fact that in 1984 Dr. Kitamura had cooperated with Dr. Takeshi Abe and discovered 23 of 48 hemophiliacs under the care of him were infected with the *HIV* through the JNIH-approved blood products. Kitamura had been secretly provided with the serums of the patients from Dr. Abe, who was later arrested and is being tried on the charge of injury which led to deaths of the patients. However, Kitamura did neither report his findings to the director and Dr. Yasuda of JNIH, nor to the responsible bureaucrats of the MHW.

10.5.4.4 Through the exchange of fax letters between Dr. Yasuda and me, he seemed to have given up his hitherto declared stance. In the fax message of 17 March 1996, having been converted, he wrote to me: "Herewith I confess to take responsibility for the AIDS disaster caused by my ignorance and opportunistic attitude, and am ready to accept any accusation."

10.5.4.5 Dr. Yasuda was only one scientist who confessed to admit the responsibility for the disaster among the JNIH leading staff. All others of them have tried to make only him alone take all responsibilities and have never apologized to the victims and public for their misdeeds. This case again revealed that some leading staff of the JNIH were not free from corruption and irresponsibility. Only Dr. Yasuda had courage to admit his responsibility, while he was reportedly blamed and isolated by his former colleagues of JNIH because of his honest confession. In July 1996 he passed away of the *Hepatitis B virus* with which he had been infected in the JNIH laboratory.

10.6 Based on these interviews and documents I wrote a paper and

have it published in one of the prestigious monthlies (Shibata, 1996a). In this paper I revealed the truth about the misdeed of the AIDS disaster as well as the confession of Dr. Yasuda, and further appreciated his honesty. It was a shocking information to the public.

10.7 My denunciation of the JNIH role in having brought the AIDS disaster found some important repercussions. Here I refer to only two of them.

First, it motivated the opposition parties to accuse the misdeed of JNIH in the Diet and to ask Mr. Naoto Kan, the Minister of Health and Welfare to investigate the role of JNIH in connection with the disaster. Minister Kan could not but confirm the irresponsible misdeed of the JNIH, and said that the JNIH did not play its expected role which is to be compared with the CDC, USA. It was later reported that he said that there would be no raison d'être of the JNIH, and that it should concentrate on research about emerging new infectious diseases. Reportedly he strongly urged the leading bureaucrats of the MHW to make the JNIH change its ambiguous name "National Institute of Preventive Health" to "National Institute of Infectious Diseases."

10.8.1 Second, my denunciation also motivated conscious researchers of the JNIH to reflect the JNIH misdeeds and to reconsider how to improve its screening work. In June 1996, in a meeting, one of them openly asked Director Yamazaki to admit the JNIH's responsibility in relation to the disaster and to learn lessons therefrom and further to reform the screening work. He added that another tragedy would occur in near future without such acts of reflection and reform.

10.8.2 To their and our surprise, Director Yamazaki refused to accept the proposal. He said, "The JNIH will never make public its official comment on the disaster caused by the unheated blood products. The lawsuit demanding to have experiments of JNIH halted is still in dispute. If JNIH has made public its comment, it would get us into trouble in connection with the suit." (Yoken-Gakuyuukai, 1996) As you see, in defiance of the critique from Minister Kan, the victimized hemophiliacs with the JNIH-approved blood products and the public, Director Yamazaki openly declared that he would never apologize to the victims and nation for the criminal misdeed of it, and that he would further let the corrupt system of screening work continue to exist for years to come. It seems that he believes as if the whole nation should serve the JNIH, not on the contrary. You will find in his words the typical expression of elitist sentiments of the JNIH-NIID privileged medical scientists as the heirs of the BW scientists.

So, JNIH could not but rename itself on 1 April 1997, one month before its 50th anniversary.

11. The implication and limitations of the international inspection at the NIID

11.1 As seen above, the lack of the science of safety as well as the sense of respect to human rights in the NIID has been clearly demonstrated with the AIDS disaster. Such a lack has also been proved in the environmental and location issue by us at the Tokyo District Court. Our stance received friendly repercussions from abroad, as well. It was noteworthy that Dr. Collins, a coordinating

editor of the WHO manual, which was often mentioned in the deliberation in the court, warmly supported our cause. In 1996 he, such an expert, kindly submitted to the Tokyo District Court his "Statement" (Collins, 1996) to the effect that it became necessary for any nation to regulate laboratories of pathogens and GMOs, and that the JNIH-NIID should relocate to a wide site where there are no residents in its immediate vicinity. Dr. Collins further scientifically considered the efficacy of the so-called containment devices and facilities as well as the HEPA filter and confirmed that such devices and facilities should not be located in built-up areas. With his "Statement" it was confirmed that our stance was founded. We were very much pleased with the fact that Dr. Collins, so prestigious expert of biosafety, supported the plaintiffs in our lawsuit. We further proposed the court to invite him as an expert witness to Tokyo.

11.2 To our surprise, the NIID arrogantly replied that Dr. Collins had no voice, because he was already not only retired, but also had no opportunity to observe the devices and facilities in the laboratories of the NIID. It motivated us to counter-propose that then the NIID should let him have the safety conditions within the NIID and the environs inspect and his report of risk assessment on the NIID submit to the court.

11.3 As a result, after a few months, the NIID could not but reluctantly accept our proposal with the condition that it invite two American scientists, Mr. V. R. Oviatt and Dr. J.Y. Richmond. Mr. Oviatt was the Head of the Environmental Health and Safety Division at the NIH, Bethesda, and is now retired in Scotland. Dr. Richmond is Director, Office of Health and Safety, the CDC,

Atlanta. Frankly speaking, we were sorry for Mr. Oviatt and Dr. Richmond (hereafter O&R) being invited to Tokyo by NIID, because its disgraceful intention was to let them counteract Dr. Collins. In order to make the inspection fare and balanced, Dr. Collins kindly recommended us his colleague, Dr. David A. Kennedy. He was a principal professional technology officer at the Medical Devices Agency, Department of Health, UK, from 1968 through to 1996, as well as a WHO advisor on medical devices. He is now an Honorary Visiting Research Fellow, King's College London as well as a Visiting Fellow, Cranfield Biomedical Centre, Cranfield University, UK.

11.4 It is in this context that the Tokyo District Court, as a part of deliberations of our suit, decided to have four British and American experts inspect the NIID. Such a procedure could be considered to be epoch-making in the history of civil rights campaigns against environmental destruction or disturbance, especially of campaigns and lawsuits in prevention of possible hazards caused by laboratories dealing with dangerous pathogens, unknown GMOs, chemicals, radioisotopes, laboratory animals, infectious waste and so on in densely populated residential areas. For the first time in the history of lawsuits as well as of scientific institutions in Japan, it was decided that foreign scientists were asked to inspect the so-called most "leading" national laboratory of pathogens and GMOs. At the same time, it turned out that there were no experts in Japan who were qualified to make such an inspection. It is a shame to Japan.

11.5 We have asked NIID to provide Drs. Collins and Kennedy with ample time and opportunities to do their work. We expected that

NIID would do the same for Mr. Oviatt and Dr. Richmond. Advised by Drs. Collins and Kennedy, we asked NIID as follows:

11.5.1 To allow them to enter the laboratories not only on June 18 when four scientists together would inspect, but also on two additional days between June 9 and 17, because they were scheduled to arrive here on June 6; besides, to let them have one day on June 19 to interview an biosafety officer,

11.5.2 To allow three scientists (Dr. Shigeo Honjo, Honorary Fellow of the NIID and Dr. Hideo Arai, Senior Researcher at it and me) to accompany them as their interpreters, and

11.5.3 To allow them to inspect anywhere and any devices which they may find to be necessary to prepare risk assessments.

11.5.4 To our surprise, NIID refused all of our requests. NIID insisted that Drs. Collins and Kennedy would be allowed to enter the laboratory only one day on June 18, that the number of our interpreters must be one, and that the rooms and space Drs. Collins and Kennedy can inspect should be restricted. NIID went further to forbid their tape-recording all voices of oral explanation and discussion during the process of the inspection.

11.6.1 The leading staff of NIID insistently asked us to accept their decision as the final one. We deplored the fact that by so deciding they lost the golden opportunity to show their fair attitude of open cooperation with the four scientists who were kindly asked to make the inspection at NIID. NIID was the inspected, not the inspector. But it was strange and rude that the inspected dared to dictate to the inspectors.

11.6.2 Besides, we asked NIID to provide Drs. Collins and Kennedy and us by the end of April with information on the items which

must be necessary for any risk assessment. These items include: site of laboratory buildings in relation to other occupied premises (houses, schools, hospitals and so on). Climate/prevailing wind; external air movements around buildings; Inside: lists of all agents in groups 2 and 3 held, whatever their use; lists of radioisotopes and chemicals in the present laboratory; storage facilities of biological agents and chemicals. Fire and emergency precautions. Animal facilities and number of animals. Number of persons (including visiting researchers, students and part-timers) working in each room and space allotted to each worker; fume cupboards; number and nature of biological safety cabinets (BSC); how is air exhausted, how are air-flows into and around them; and how often they are tested with what results; method and frequency of filter tests; dispersion of effluent air, and so on.

11.6.3 To our regret and surprise, NIID failed to provide us with the information about these items. It is impossible for any experts on biosafety, risk assessment and EIS to make a scientific inspection under such conditions.

11.6.4 We proposed to NIID that O&R should observe NIID not only from the side of NIID but also from the side of residents and Waseda University (WU) and that they should listen to our explanation on the background of our campaign regarding the bad smell, escaping lab animals, and the story of six WU professors who in the 1980s died of cancer possibly caused by the exhaust air from the National Institute of Nutrition (NIN) which had been located at a site just west of WU since the middle of the 1940s. But the NIID replied that O&R should not be concerned with the environs such as the locations of the houses, WU, the facilities for

the handicapped, the hospitals and so on.

(Now NIN as the renamed National Institute of Health and Nutrition [NIHN] is located at the east part of the same site adjacent to Shibata's site. The story of the six WU professors was already reported in the Weekly *Shukan-bunshun*, 10 August 1995, one of the leading weeklies in Japan. By the way, the JNIH shares the same building with the NIHN and the National Institute of Health Services Management. Nobody would dare to contend that such sharing is appropriate from the standpoint of safety for the staff of the three institutes and the public.)

11.7 Needless to say, in the UK an inspection of a laboratory such as NIID is performed by the HSE without prior notice. It is natural. But in the case of the NIID, several weeks before the inspection the date was fixed as June 18. So, the leading staff of NIID could try to make the laboratories have an appearance as if these were compatible with the regulations of the WHO manual.

11.7.1 So, for the several weeks before the inspection, all staff of JNIH were ordered to make all laboratories neat, clean and free of materials that are not pertinent to the work. They were also asked to transfer all useless devices, articles, junk and corrugated cartons out of laboratories to the non-inspected rooms. Open-toed footwear had been advocated in the testimonies by Drs. Kitamura and Yamazaki. But this time all staff were given closed-toed footwear, following the WHO manual (WHO, 1993, p. 9). Thus, the inspection meant a great deal to the safety of the staff. We were pleased with the fact that our lawsuit also contributed something toward improvement of safety in NIID.

11.7.2 Whatever the leading staff pathetically tried to make the

laboratories neat and clean, however, their effort was limited, because its site is so small that the structural defects such as narrowness, overpopulation and so on of the laboratories, including most of Level 2 ones, cannot be rectified.

11.8.1 Just before the inspection began on the morning of June 18, NIID went so far as to forbid photography on the site, despite the fact that there was not such an agreement at the court.

11.8.2 NIID had insisted that there should be only two interpreters, that is, Dr. Honjo on behalf of the plaintiffs and Dr. Kurata for the defendant. However, Dr. Kurata was accompanied by several aides, including one representing TBS, a company under contract with NIID.

11.9 It is no wonder to us and the public in the light of the numerous unfair and corrupt misdeeds committed by JNIH that NIID went to extremes to ignore even the agreement reached at the room of the judges of the Tokyo District Court. We only deplore the fact that the leading staff of NIID again dared to show their unfair attitude to the British and American inspectors. It is a shame. I am convinced that any inspector at a laboratory of pathogens and GMOs has never before experienced such an unreasonable attitude of the inspected in respect to preconditions of inspection. Under such restrictions the international inspection by the two groups of scientists took place on June 18, 1997.

12. Two different and opposing reports of the inspection

12.1.1 The deadline for the plaintiffs and the defendant to submit each report of their invited inspectors to the court was Friday, 29

August 1997. We submitted the report by Drs. Collins and Kennedy (hereafter, C&K) and its Japanese translation to the court on 28 August. On the next day, the NIID received them from the court. But it was on 10 September, that is, 12 days later than the deadline that NIID submitted the O&R report and its Japanese translation to the court.

12.1.2 Why? It suggests that there is a possibility for the leading staff of the NIID to have faxed the C&K report to O&R to have several comments to counteract the former added to their original report. It does not seem to be accidental that O&R mentioned the location issue of the NIH, CDC and USAMRIID, and also explained the "reason" about "the absence of many workers from the laboratories," and, besides, there are so many contradictions in their short report.

12.1.3 As I understand, Americans, Europeans and Japanese always date an important document, when they sign it. But it is strange that there is no date in the O&R report. I think that there is a possibility that O&R intentionally did not date it, or the leading staff of NIID erased a date in the original text.

12.1.4 Already during the period from the end of July to August it was reported that some leading staff of NIID, with much satisfaction, had reported about the O&R report to their staff. It is also reported that an expert of biosafety at an international organization had received a copy of the O&R report already in the middle of August. Therefore, I infer that there are two versions of the O&R report, that is, an original version with a date of July or August and another revised one without a date or with a date of September, which was perhaps erased by the leading staff of NIID.

The second one was perhaps rewritten by O&R after they received the C&K report through fax from NIID. Only with such a hypothesis we would be able to understand the reason why NIID submitted the O&R report and its Japanese translation 12 days later than the deadline to the court. I think we need not be surprised in the light of many misdeeds of the NIID that it so unfairly and meanly behaved. As to many disgraceful misdeeds of the JNIH-NIID, see the other papers of mine (Shibata, 1997a, 1997c and the present paper, 10 above).

12.1.5 There are over ten wrong words, which were intentionally mistranslated, in a Japanese text of the O&R report. For example, the word "cities" of Atlanta, Bethesda and Frederick (Oviatt and Richmond, 1997, p. 3) is translated to a Japanese word, "shigaichi," which means "streets of offices, shopping and residential areas." Nobody would think that the CDC, NIH and USAMRIID are located in such areas.

12.2 We carefully examined the C&K report (Collins and Kennedy, 1997a) with much admiration. As expected, the report deserves to be regarded as a model of a scientific inspection of a laboratory of pathogens and GMOs.

12.2.1 It mentions the restrictions imposed on them. It is natural that C&K, as the scientists who sincerely made the inspection at the controversial laboratory, could not but report on the restrictions so unfairly and unreasonably imposed on them as well as some possible limitations of their report. A true and sincere scientist always knows and admits his or her limitations, because an act of discovery of a truth is nothing but an act of discovery of its limitation.

12.2.2 Besides, the C&K report writes: "We saw very few of the laboratory staff at work during the inspection and we understand that some staff were away from NIID attending a conference or were otherwise absent with the agreement of the management. It was impossible to conduct a through inspection of containment measures without being able to see a normal complement of staff at work, particularly to assess the efficacy of working practices." It suggests that the leading staff of NIID surely asked most of their staff to "evacuate" from their laboratories on the day of inspection, because otherwise the inspectors should have been surprised to find the laboratories too much overcrowded.

12.2.3 In spite of these limitations, the C&K report confirms:

12.2.3.1 It notes certain difference between the NIID and Europe in classification of pathogens. NIID classifies many dangerous pathogens as Level 2, that is, not so risky to individual and community, whereas at least 15 pathogens of them are classified as Level 3, that is, risky to individual and community in European standards. It means that NIID dares to deal with more dangerous pathogens in the residential area than in Europe.

12.2.3.2 NIID deals with the agents of "viral haemorrhagic fevers" which should be classified Level 4, that is, most dangerous to individual and community, and should be handled only in Level 4 containment facilities in European standards. But in NIID these agents are handled in Level 3 laboratories in the most densely populated area.

12.2.3.3 "Many laboratories, even without workers present, were very cramped and there was much clutter of equipment on benches, with little working space." The report confirms: "We consider that

under such cramped and overcrowded conditions, accidents are more likely to occur with a risk of release of pathogens and other substances hazardous to health. In general, equipment likely to move in an earthquake was not fixed and...in some cases items of equipment were stacked, thus exacerbating the risk of toppling over." The report mentions many examples of the violations to the international regulations recommended in the WHO manual.

12.2.3.4 C&K examined the rooftop cooling plant for air conditioning system. "The cooling plates, over which water trickled, appeared to be dirty and corroded and we saw a jelly-like deposit that suggested colonisation by micro-organisms....The general appearance of the cooling plant suggested that there could be build-up and release of *Legionella* species into the environment, thereby to be a serious health hazard." This findings casts serious doubts about the quality of supervision of the work of the commercial company which is contracted to maintain this and other important plant within NIID.

12.2.3.5 The report critically examines the lack of overall risk management in NIID. The Director-General does not seem to have a personal responsibility for the health and safety of NIID staff and the local community. It confirms: "Unlike the situation in the UK, there appears to be no single person who has overall responsibility in this Institute for biosafety."

12.2.3.6 The report refers to a recent WHO publication on safety in health-care laboratories (WHO, 1997), which states that:

- wherever possible laboratories should be sited away from patient, residential and public areas, although patients may have to attend and provide or deliver specimens.
- high-level containment or high-risk laboratories should be located

away from patient or public areas.

12.2.3.7 Thus, it concludes: "In the light of our observations, the answers that we received to questions and questions that remain unanswered, we consider that on the day of the inspection NIID was definitely not in a position to guarantee that its location and activities were not a risk to public health and safety."

"NIID was certainly not able on the day of the inspection to get anywhere near to convincing us that it presented a low order of risk to public health and safety. Moreover, we consider that if NIID cannot effect sufficient improvements in its containment measures and management system to satisfy the concerns of local residents, it should think seriously about relocation to an area where there are no residents in its immediate vicinity to be put at risk by its location and activities."

12.3 On the other hand, how does the O&R report, on behalf of NIID, examine the NIID?

12.3.1 In contrast to the C&K report, the O&R report mentions nothing about the limitations of their inspection. It sounds as if O&R knew everything and were almighty in their evaluation of the so-called "safety" of NIID. Such an attitude itself throws doubt on the sincerity of the O&R report.

12.3.2 At the very beginning of the report, O&R insist, "The NIID poses no biosafety threat to the outside surrounding community as a consequence of its work with infectious diseases. No serious breaches in biosafety were observed." But nobody can find any substantial proof of such an argument in their report. Needless to say, the concept "biosafety threat" means the threat not only of apparent and latent infections with pathogenic microorganisms but

also of cancer risk with carcinogenic microorganisms, GMOs, chemicals, radioisotopes and so on. How could O&R demonstrate the above mentioned thesis with so many restrictions and limitations and without any information about the items, which were requested by us to NIID (see, 11.6 above).

12.3.3 O&R write, "the guidelines published by the WHO, *Laboratory Biosafety Manual,* and the CDC/NIH (USA) guidelines, *Biosafety in Microbiological and Biomedical Laboratories* were used as the recognized standards and basis for this report." But some theses of their report throw doubts on their sincerity. It does not seem that they carefully read the WHO manual itself. (As to the CDC/NIH manual, it may be valid to laboratories in the USA, but not always to the ones in other countries. Therefore, we deal with only the international regulations, typically represented by the WHO manual.) Allow me to mention only two of their wrong arguments as follows:

12.3.3.1 One of the most controversial issues in our campaigns is the location issue of the laboratory which always discharge exhaust air which include microorganisms as well as chemical and radioactive particles. Therefore, we cited the warning of the WHO manual and other important sources (3.2.1 above). But O&R completely ignored such sources and inspected nothing about the exhaust air from the NIID laboratory, not to speak of the efficiency of hundreds HEPA filters and the percentage of the defective ones as well as an expected EIS about the exhaust air.

12.3.3.2 The O&R report writes: "The question has been raised regarding the suitability of having *acoustical tile ceilings* in BSL/P2 laboratories. This type of ceiling material is perfectly acceptable at

this biosafety level." (Oviatt and Richmond, 1997, p. 4, emphasis added) Such argument itself is non-sense. Nobody would think that what is called "acoustical tile ceilings" is essential to biosafety in Level 2 laboratories. We have never raised such a question. Only NIID did do so.

In contrast to their argument, the WHO manual regulates as one of the design features of basic laboratories (Level 1 and 2 laboratories) as follows: "Walls, ceilings and floors should be smooth, easily cleanable, *impermeable to liquids, and resistant to the chemicals and disinfectants* normally used in the laboratory" (WHO, 1993, p. 10, emphasis added).

In our suit, the leading staff of the NIID often insisted that all conditions, including the design features, in their laboratories were perfectly compatible with the WHO manual. We, the plaintiffs, refuted such an argument and proved most of the conditions incompatible with it. But we have never insisted that the ceiling material should be acoustical. It seems to me that the O&R argument on the so-called "acoustical tile ceilings" issue suggests that they have not read even the WHO manual.

12.3.4.1 It is interesting that even O&R can not but propose a number of improvements to NIID. Of course, we agree with them when they do so. But they should know that thereby they have completely bogged down into contradictions. The reasons are as follows:

12.3.4.2 Most of their proposals suggest that NIID violates the WHO manual.

12.3.4.3 O&R recommend the three options for "long-term opportunities for improvement" to NIID as follows:

1. Reduce the amount of equipment, extraneous materials.
2. Provide additional laboratory space.
3. Provide organized storage space for supplies outside the laboratory.

But it is impossible for NIID to realize these in such a narrow laboratory at such a small site. In order to follow the advice, NIID unconditionally has to relocate to new larger buildings in a vast site.

12.3.5.1 Under the heading of "Positive Findings" in the O&R report, they only repeat what they heard from the leading staff of NIID.

12.3.5.2 Most of the "positive findings" of O&R are only what they heard from NIID or in contradiction with what they wrote in the same report. They have never been verified by O&R themselves, or are refuted with their own proposals for improvements.

12.3.5.3 O&R evaluate greatly the "Rules on Safety Management of Pathogens of the NIH." But, as a matter of fact, NIID did not provide the four inspectors with English translation of its rules. Therefore, C&K are right and honest, when they write, "We have seen a copy, in Japanese, of these rules and would also be interested to see an English language copy of them," while O&R are not sincere and honest, because they know nothing about the contents of the rules in Japanese.

12.3.5.4 In order to verify most of their "positive findings," the time of the investigation was so limited. In so short time it was impossible.

12.3.6 Let us omit what O&R heard from the leading staff of NIID and their subjective and non-verified opinions from their report, and

leave only what they really inspected. It will clearly turn out that their report is very short and rough, and that NIID is dangerous in so many respects even in the light of the O&R report, not to speak of the C&K report. In this respect, the O&R report deserves rather to be evaluated by us, the plaintiffs and the concerned public.

12.4 Is the stance of the O&R report scientific? In one of my papers on the international inspection (Shibata, 1997e) I already reported about the implications of it as well as the poverty of the O&R report. In another paper which will soon appear in a science journal in Japanese, I am going not only to analyze lots of contradictions in the O&R report, but also to explain some reasons why there are so many differences between C&K and O&R.

12.4.1 First, there is a difference between their scientific stances and methods. "De omnibus dubitandium." ("Every thing deserves to be doubted.") I am convinced that this famous maxim from ancient Rome is one of the most important touchstones of the scientific method and attitude. Without such a stance any science, especially a science of safety, including biosafety, cannot exist. In this respect, I evaluate very much the C&K report, because it mentions so many doubts. In contrast, it seems that O&R do not know how to doubt what they heard from the leading staff of NIID about the safety and environment issues of the NIID. *They only believe and repeat* what they heard from them.

12.4.2 In Japan there have been many versions and variations of the so-called "myth of safety" in the fields of chemical, radioactive and biological hazards, not to speak of car, flight and other accidents. As to biological hazards, we have submitted to the public a long list of them, including the deadly hazards with wrong vaccines and blood

products screened and approved by the JNIH-NIID. Therefore, we have much experience with many versions and variations of the "myth of safety," while we, Japanese scientists, who have tried to apply the theory of human rights to life, health and safety to prevention of hazards and accidents, have developed the science of safety. I, myself, tried to describe an outline of the science of safety and applied it to the JNIH-NIID issue (Shibata, 1997d).

12.4.3 Therefore, the arguments delivered in the O&R report are not new to us. I think that we can regard the C&K and O&R reports as a typical textbook of the science vs. the myth of safety. In fact the both reports are being used as such a textbook and carefully studied by some of our scientists who teach the science of safety to students at universities. I believe that the reports as such a textbook will attract much attention from university teachers, lawyers, civil rights activists and students in this country. We need not be surprised that the leading staff of the NIID, who, with their myth of safety, brought so many biological hazards to babies, children, hemophiliacs and others, asked a help from such American believers in the myth of safety.

12.4.4 Second, the differences might also be explained by the different systems in the UK and the USA. There is a legal system of registration and inspection of laboratories of pathogens and GMOs at and by the HSE (the governmental Health & Safety Executive) in the UK, while there is not such a system in the USA. In the UK there has been and is a good tradition of "rule by law" as well as the excellent system of "industrial inspectors," whose sincerity, honesty and deep concerns about the safety of the workers and public were highly admired and evaluated by K. Marx in his

book *The Capital.*

12.4.5 In the USA, to my knowledge, without publication of an EIS asked by the NEPA and the public consent, new laboratories, including the Level 3 laboratory in the Proving Ground, the Utah Desert as well as the Level 2 laboratory of the UCSF, could not be set up. It is a positive aspect in the USA. But in the USA there is no governmental inspection agency like the HSE, the UK. This is a negative aspect.

12.4.6 In this context, on the one hand, C&K, authorized by the law, have much experience in inspecting or making risk-assessments of laboratories and medical devices from the standpoint of not only researchers but also the public. C&K might be called the "industrial inspectors" in the age of emerging new pathogens and GMOs.

12.4.7 On the other hand, I think, O&R have had neither experience nor know-how of inspectors in the light of British standards. They have paid attention only to the safety issue within laboratories, but not to the location and environmental issues. O&R have been concerned with only safety of workers within laboratories, not of the public. I am sorry that they have the same indifferent and irresponsible attitude as the leading staff of the NIID toward the residents and the public around the NIID.

12.4.8 Thus, the stances of C&K and O&R are quite different. Therefore, it is no wonder that the evaluations and conclusions of the British and American scientists in the field of safety including biosafety are quite different.

12.5 Maybe the O&R report seemed to be so unreasonable and absurd to the eyes of C&K that the former touched the conscience of C&K as the sincere and responsible scientists. It perhaps

motivated C&K to make critical comments (Collins and Kennedy, 1997b) on the former. Here I do not describe the outline of their comments. I only evaluate their comments as a model of scientific examination of the opposing report. Their fair, balanced and open-minded comments are greatly appreciated. Mr. Oviatt and Dr. Richmond, if possible, are kindly invited to submit their sincere and scientific comments on the C&K report and comments. I think that it is their moral obligation to Japanese people as well as to the scientific community in Japan and throughout the world. Unless O&R could do so, it would be natural in the light of morals and bioethics for them to call off their report not only from the Tokyo District Court but also from the courts of the public opinion, the scientific community and the history.

12.6 Last but not least, the above mentioned WHO publication (12.2.3.6) deserves to be noted. To my knowledge, for the first time in the history of the international regulations toward prevention of biohazards, the location issue has directly and officially been paid attention in the WHO publication. We are pleased with the fact that at last, our stance has been publicly approved and supported by the common sense of the international community.

13. Perspectives

13.1 What are to be expected as the perspectives for the civil rights campaigns against the wrong location of the NIID as well as for the enforcement of legal regulations against laboratories of pathogens and GMOs in Japan?

13.2.1 Please be informed that we, the residents, WU and the

concerned scientists and public have never intended to attack JNIH-NIID. We have only asked for scientific and bioethical explanation and dialogue in defense of the right to informed consent. Nevertheless, JNIH-NIID went so far as to attack us by violence of the riot police. In this situation, we could not but defend ourselves by the lawsuit and the campaigns.

13.2.2 Here, we would also like to point out another important aspect of JNIH-NIID, which might be regarded as a victim of the poor science policy of the MHW and our government, as well. For example, the number of researchers at the JNIH was 338 in 1977, but 312 in 1995. In this age of emerging new pathogens, the number of researchers has been curtailed year by year. For this, the MHW is accountable. Development of the NIID by increasing number of staff is urgently needed to meet the threat of newly emerging pathogens, but this can not be met as far as NIID has to stay in such a narrow laboratory on such a small site.

13.2.3 One major step that could be taken toward a desirable development of NIID would be to integrate the main laboratory (Toyama, Shinjuku-ku) and the branch laboratory (Musashi-murayamashi City in a suburb of Tokyo) into a new and larger laboratory. Until today, the staff of the main laboratory have mainly performed experiments with pathogens and GMOs, whereas the staff of the branch laboratory mainly screening of biological products. Thus, the separation between sections of research and screening has been one of the reasons why so serious misdeeds have been committed by JNIH-NIID. It was one of the reasons why JNIH until 1985 continued to attach the governmental label "Approved by NIH" to unheated deadly blood products (10.5 above). An integrated

laboratory with the two sections would better be able to contribute toward the promotion of public health.

13.2.4 Deeply understanding the implication of our campaigns and suit, Drs. Shigeo Honjo and Hideo Arai have unselfishly, bravely and publicly cooperated with us. Their aims are to promote not only the public health and ecological protection but also to improve the poor conditions of research and biosafety for their colleagues. They, from the standpoint of biosafety and bioethics, have consistently spoken out for the residents' rights to environment, health and safety and appeared as expert witnesses on behalf of the plaintiffs before the court. They deserve to be called "the salt of the earth" in the JNIH-NIID. They represent a positive, science-mission-oriented and conscientious aspect of some researchers at JNIH-NIID. They are unselfish volunteers on behalf of many anonymous colleagues who are dissatisfied with narrowness, overpopulation and the poor conditions of research and safety in the laboratories.

13.2.5 Please be also informed that we have never opposed the research of pathogens and GMOs as well as the NIID itself. We have only opposed the inappropriate siting of NIID and its infringement on human rights of our citizens. We only hope that the leading staff of NIID will change their hitherto declared arrogant, privileged and unreasonable attitude toward the residents and public, that the number of NIID researchers will be redoubled in a new and larger laboratory at a new, vast and non-populated site, in accordance with the international regulations and the C&K report, and that thereby it will contribute much toward promotion of the public health.

13.3.1 What will be achieved when we win the case in the present

lawsuit? Needless to say, first, it would contribute very much toward the development of the NIID itself, because the MHW will immediately and strongly be asked by the public and mass media to provide NIID with a vast non-residential site and a new and larger laboratory. For the past ten years we could not but accuse JNIH of its undemocratic and unreasonable attitude which it could take only by the backing of the riot police as well as the political power.

13.3.2 It would also provide the handicapped people in Tokyo with a golden opportunity. After WWII the site of the headquarters of the BW network was used as a site of the National Center for Rehabilitation of the Handicapped (NCRH) attached to the MHW. But the MHW, unreasonably and inhumanely ignoring "inconvenience of communication" of the handicapped, had moved NCRH to Tokorozawa City in a suburb of Tokyo by the end of the 1970s. Without any agreement of the residents, handicapped people at the neighboring two welfare facilities and WU as well as the Mayor and the City Assembly of Shinjuku-ku, however, the leading staff of JNIH immediately and secretly managed to have the right to use the site transferred to their own on the pretext of "convenience of communication" for them. As a matter of fact, the leading staff of JNIH for their own interests usurped the right of the handicapped to the continued use of the site. This represents another serious infringement of human rights committed by JNIH on the handicapped. Therefore, it is reasonable and legitimate that the present buildings of NIID will be reused as a welfare facility for them. The public have nothing to be worried about such reuse.

13.3.3 It is noteworthy that NIID has been regarded as the "best model" of the standards of biosafety by almost all other laboratories

in Japan. Therefore, it does not take much imagination to think how poor and dangerous the sites, safety conditions and practices of over 500 other biotech laboratories in Japan are, because it is said that JNIH has played a leading role in guiding the safety standard of these laboratories. It is in this context that we have for so many years been struggling for human rights to life, health and safety not only of the residents in the area around NIID but also of the public throughout Japan. Therefore, the C&K report on the NIID should be regarded as a serious warning not only to the resident around it but also to almost all people around all other laboratories in this country.

13.3.4 As I wrote above, Japan is unregulated, as far as the international regulations on the location and environmental as well as biosafety conditions are concerned. Accordingly, we filed the suit in order to have the international regulations implemented in this country. One of the aims of our suit is to seek a court order to the government for the legislation of a system like the one in the UK in which the safety of these laboratories and the residents can be secured. If our court has sincerely considered the warnings from the C&K report and the concerned scientists and public all over the world, it has to urge our government to implement the international regulations including the WHO manual and the above mentioned WHO publication. The laboratories will be requested to respect the principles of due process and informed consent in connection with the location and environmental conditions. It will be difficult for any laboratories to mobilize the riot police to suppress the concerned residents.

13.3.5 Last but not least, for the past fifty years almost all the

population of Japan have been victimized by the misdeeds committed by the JNIH-NIID, including human experiments, hazardous vaccinations, improper "screening" of dubious vaccines, blood products and antibiotics, corruption and so on. Such misdeeds can be explained only in terms of the inhumanity which has traditionally characterized the JNIH-NIID as the heirs to the legacies of the medical scientists who cooperated with the BW network during WWII. The civil rights campaigns here and abroad would surely motivate the leading staff of JNIH-NIID to reflect on what they have inherited from their teachers as war criminals. Behind Drs. Shigeo Honjo and Hideo Arai, there are many anonymous but conscientious researchers. They will be encouraged to be united to democratically reform NIID.

13.4 If our court should happen to favor the present site of JNIH-NIID, which seems to be quite unlikely, it would predictably encourage every development adverse to the above expected promotion of public health, environmental protection and improvement of biosafety in NIID and almost all other laboratories of pathogens and GMOs, as well as development of NIID itself.

13.5.1 Finally, I would like to stress the implications of our civil rights campaigns for the international community. As repeated above, in Japan there is neither a system of registration and inspection of laboratories of pathogens and GMOs like the one in the UK, nor a system of EIS like the NEPA in the USA. Japan is only one unregulated country of such laboratories among the developed countries. We now live in the age of emerging new pathogens and unknown GMOs. Let us imagine the worst scenario in which residents around the NIID may be infected with emerging, new

and unknown pathogens and GMOs and an outbreak of them occur at the very center of the most densely populated areas in Tokyo. Such pathogens and GMOs would immediately cross borders and spread to all corners of the world. Such a scenario has already and tragically been realized, as you have seen the cases of the *HIV*, *E. coli O-157*, the "Mad Cow Disease" and so on. In this respect, the warning of the C&K report is serious and does mean a great deal not only to Japanese but also to all humanity.

13.5.2 In this respect, it would be no exaggeration to say that human rights in the age of emerging new pathogens and biotechnology will surely depend on the results of our and your civil rights campaigns here and abroad. Your concerns will be greatly appreciated.

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References in Japanese on the location and safety issue of JNIH-NIID:

1. Besides Shibata's three books mentioned in the above references, there are five books in Japanese written by other leading scientists in the fields of environmental, safety and medical sciences as well as the theory of human rights. There are also

more than fifty papers written by more than twenty leading scientists and journalists in these fields. Most of them appeared in several leading scientific journals, including ones published by Asahi and Mainichi, two of the Big Three newspapers.

2. Only one paper written by Dr. Akira Oya, the then director of JNIH, appeared in the monthly *Science Asahi*, January, 1989. It was immediately criticized and refuted by Dr. Hideo Arai in *Science Asahi*, April 1989. Since then, to my knowledge, no paper advocating the inappropriate siting of JNIH-NIID, not to speak of a book, has been published.
3. As to the newspapers, there are numerous articles criticizing the wrong location of JNIH-NIID. Very few advocating JNIH appeared.
4. Thus, the location issue of JNIH-NIID will surely be documented as one of the most important events in the history of science as well as the history of civil rights campaigns and lawsuits in Japan.
5. As to the many misdeeds committed by JNIH, there are a lot of references mentioned in another paper (Shibata, 1997a).

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