White Paper¹ “Health Damage from Humidifier Disinfectant²”

At a Glance (English) Summary of Humidifier Disinfectant Disaster and its Lesson

- World’s First Mass Killing by (Mal-used) Biocide in 21st Century

Humidifier disinfectant is a commercial biocide, and public health damage from the mal-use³ of biocide has been an unprecedented disaster in Korea, or even worldwide. In this disaster, biocides, which are supposed to kill only microbes or bugs, have killed humans instead. As the products were used in fact to become healthier, the deaths and health damages incurred by those products were such a tragedy that our society had never expected.

Large major companies, not small ones, have manufactured and marketed these humidifier disinfectants, so that the raw materials were either imported or supplied by SK Chemical of Korea, and blended by Multinational companies such as Oxy Reckitt Benckiser⁴ or LOTTE Mart chains with its own Private Blend and so on. Ever

¹ This White Paper is published by RIIC(Respiratory Injury Investigation Committee) of KCDC(Korean Center for Disease Control), Ministry of public health and welfare, in Dec 2014 covering the events of 2011~2014 around the 1st investigation of Korean government. From the 2nd investigation has been conducted by Ministry of Environment.
² Some media call this ‘humidifier sterilizer’
³ ‘mal-use’ means not for the consumers, but for the manufacturers and government
⁴ Here is a summary of death toll and living patient cases who used UK company Reckitt Benckiser’s product and Denmark company Cefu’s product.(data from 1st and 2nd government investigation)
since the first product was sold in the market in 1994, more than 20 such products were marketed, and over 8 million people have been estimated to use the products for 18 years.

The humidifier disinfectants have become widely used or even a necessity in many households from the early part of 2000’s. In retrospect, health victims had appeared from the early part of 2000’s, especially among infants and pregnant mothers, and since 2006, the intensive care units of major hospitals were bustling with 4-5 cases of the same unknown disease in every early spring, but physicians and government couldn’t figure out the real problem.

In the meantime, the problems grew bigger, and they emerged over the surface. In March 2011, more than 10 patients of the same conditions were admitted to ICU of one major hospital at the same time. Most of them were young mothers just before or after the delivery with unknown mysterious disease.

The patients were in very grave conditions but unresponsive to conventional treatments, and it was decided to report the cases to Korean Center for Disease Control (CDC) for fear of unknown epidemic. The samples were sent to Korean CDC for the test of wide range of microbial infections, but still the cause was undetermined except that microbial cause was unlikely.

Based on the radiologic and pathologic findings of patients, clinicians began to suspect toxic inhalation injuries as the underlying cause. Most of the patients were either young women just before or after the delivery or infants with similar conditions in pediatric wards, and both patient groups share the same characteristics of spending most of their times indoor. The time of the year was clustered for most cases around from late winter to early spring, suggesting some potential problems in indoor environments during winter seasons. Based on these findings, Korean CDC conducted a case–control study, and a significant association was noted with humidifier disinfectant use. Animal experiment was soon carried out to confirm epidemiological findings.

In order to draw conclusions before another winter season coming, both acute but preliminary and sub chronic but standard tests were carried out simultaneously. In both tests, toxicity of humidifier disinfectants was confirmed. Based on these findings, the Ministry of Health and Social Security had issued an emergency order to recall the products from the market. After this emergency recall order, no further cases have been reported from the prospective nationwide monitoring of adult and pediatric patients in ICUs.
Official Diagnosis of 127 Definite and 41 Possible Cases including 75 deaths

Lung Injury Investigation Committee (LIIC) was formed in 2013 to collect all the relevant evidences of humidifier disinfectant toxicity and to officially diagnose cases of lung injury by humidifier disinfectants out of all the potential reports submitted to the committee. The committee was organized under the Korean CDC, and consisted of members from both government and civic society, including physicians, toxicologists, and environmental researchers who were involved in the treatment and investigation of humidifier disinfectants health damage.

LIIC have set the review process and also the diagnostic criteria for exposures as well as clinical manifestations. In July and August, 2013, LIIC began to investigate the environment of households of reported cases and also examined the survivors with high resolution computer tomography. All the previous medical records as well as new examination results were collected together with environmental assessments, and reviewed according to the diagnostic criteria, and the cases were classified according to the likelihood of humidifier disinfectant induced lung injury.

In this review process, health assessments covering radiologic, pathologic, and clinical areas and environmental assessments on the usage of and exposure to humidifier disinfectants were conducted independently from each other, and later summarized and analyzed to check for its overall validity by epidemiologists. In principle, each separate review was conducted independently by at least 3 professionals who have in-depth knowledge and experience in the relevant fields.

The result of government’s 2nd investigation was released 2015 April. Here is a summary table with the 1st and 2nd government investigation. The 3rd investigation is on-going by the end of 2015.

<table>
<thead>
<tr>
<th>구분</th>
<th>total (100%)</th>
<th>Definite 1st grade (100%)</th>
<th>Probable 2nd grade (100%)</th>
<th>Possible 3rd grade (100%)</th>
<th>Unlikely 4th grade (100%)</th>
<th>Impossible to judge (100%)</th>
<th>etc</th>
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<tbody>
<tr>
<td>1st investigation (13.7~14.4)</td>
<td>361 (100%)</td>
<td>104 (35.7%)</td>
<td>129 (43.8%)</td>
<td>43 (11.9%)</td>
<td>18 (17.3%)</td>
<td>10 (9.6%)</td>
<td>7 (19.3%)</td>
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<tr>
<td>2nd investigation (14.7~15.4)</td>
<td>169 (100%)</td>
<td>36 (16.6%)</td>
<td>28 (57.1%)</td>
<td>21 (41.7%)</td>
<td>12 (37.1%)</td>
<td>5 (28.6%)</td>
<td>98 (80.6%)</td>
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<tr>
<td>1st + 2nd investigation</td>
<td>530 (100%)</td>
<td>140 (26.8%)</td>
<td>157 (42.9%)</td>
<td>69 (21.2%)</td>
<td>23 (8.4%)</td>
<td>81 (30.2%)</td>
<td>240 (45.3%)</td>
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<tr>
<td>additional registering (till 15.12)</td>
<td>530 (100%)</td>
<td>140 (26.8%)</td>
<td>157 (42.9%)</td>
<td>69 (21.2%)</td>
<td>23 (8.4%)</td>
<td>81 (30.2%)</td>
<td>240 (45.3%)</td>
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Registered humidifier disinfectants users and 4 categories certification by Korean Government

Ministry of Environment
Out of the review of 361 cases in total, 127 (including 57 deaths) were classified as definite, 41 (including 18 deaths) as probable, 42 (including 9 deaths) as possible, 144 (including 18 deaths) as unlikely, and 7 (including 2 deaths) as unclassifiable. The results of LIIC review were announced publicly in March 2014, and notified to each individual.

- Tearful Struggle for Redemption of Damage by Victims together with Civic Groups and Media

On August 31st, 2011, the Korean Government had announced the results of epidemiologic studies of health damage from humidifier disinfectant, but had no plans for the management or redemption of affected victims. None of companies that manufactured or sold the products had acknowledged any responsibilities, nor conveyed apology or plans for compensation.

Faced with these irresponsible behaviors, victims have sought the help of civic groups, and together they have led a long struggle to demand appropriate responsibilities and fair compensation through series of street demonstrations and press conferences in front of manufacturing companies, Government Ministry, and Parliament. Victim groups organized more than 200 individual demonstrations in front of the Gwanhwamoon (central downtown boulevard), and filed civil and criminal suits against humidifier disinfectant manufacturing companies.

In response to these demands of victims, the General Assembly of the Parliament had adopted a resolution to introduce a special compensation law and to have the Government to expedite its relief measures for victims. The 18th Parliament had started their discussions for humidifier disinfectant victims and these continued to the 19th Parliament. Subcommittees of ‘Health and Welfare’ and ‘Labor and Environment’ played a pivotal role in submitting a series of legislatures for relief of humidifier disinfectant victims.

However, Government Ministry had instead amended the enforcement regulation of Environment Health Act so that Government can pay the very basic minimum costs of care and funerals for certified victims only and keep the indemnity rights against the companies. With these measures, no further discussions could continue to extend the proper relief to all victims by a special compensation law.

Civic groups have made extraordinary efforts to solve the humidifier disinfectant disaster. When Government showed no intent in the investigation of potential victims,
members of Korean Society of Environmental Health together with other civic groups had volunteered to visit more than 100 households of potential victims to investigate the scope of the disaster. Members of Korean Society of Environmental Health and Toxicology, another professional body, had reviewed all the available toxicology data of every ingredient of disinfectants and reported an unacceptable level of health risks. The report indicated a finding that if only a basic but proper risk assessment was conducted by manufacturing companies or regulatory bodies of Government, these disasters could have been reduced or even prevented.

Mass media had focused on the personal stories of individual victims and thereby tried to show the true nature of this tragedy. Programs of current affairs of major broadcasting companies, internet media like Pressian, and professional media like Baby News were leading in the reports of these cases. During April and May of 2013, the Kyunghyang Shinmun published a special series of front page and entire page articles for more than 10 times to reveal the hidden aspects of this disaster.

Many different civic groups have organized and advocated victims to solve the problems. With Asian Citizen’s Center for Environment and Health in front, Korean Federation for Environment Movement, Green Consumer Solidarity, and Women Environment Solidarity have all tried to solve the problem. Victim groups had shared the information on the damage and its investigations in the internet café well before the results were available.

After the Government announcement of the reports, victim groups have formed an association of “Humidifier Disinfectant Victims and their Families”, and played an active role in demanding proper management of damages. However, the manufacturing and marketing companies have not yet acknowledged their responsibilities at all, and victim groups had to fight individually divided legal battles against these giant companies and the Government.

- Disaster by Home Environment Products originating from Company Complacencies and Policy and Institutional Inadequacies

Why in Korea, unprecedented in other parts of the world, have occurred this horrible mass killing and health damages by humidifier disinfectants? Many experts have offered diverse analysis to this question. First, the companies in Korea have focused only on the utility of the product, without any proper regards to the health and safety issues, in developing a new chemical product. Next, inadequacies were indicated in Government policy and institutional measures in supporting the effective and safe management of chemicals.
Especially big deficiencies were indicated for Toxic Chemicals Control Act and Quality Control and Safety Management of Industrial Products Act. While changes in residential environments with the appearance of multi-story apartments brought the increased use of humidifiers, the heightened interests in health and hygiene together with the blindfolded trust in technology and its convenience were parts of the underlying socio-cultural backgrounds of this disaster.

One of the fortunate aspects of this tragedy was that the time taken from the recognition, then the investigation, of this problem to partial resolution by emergency recall order was relatively short. However, because of the urgency and time constraints in the investigation of the cause, some deficiencies were also noted. The epidemiologic studies were short in covering the presence of mild cases, sensitive groups, and sequelae or complications.

In toxicology tests, inadequacies were indicated in the area of discriminating power of cytotoxicity tests and elucidation of lung fibrosis mechanisms. In simulation studies of exposures, no detailed analysis was conducted for the ingredients of the products. In CIIT review process, difficulties in diagnosis were insurmountable for some cases with inadequate records, and the coordination of clinical and environmental assessments was left for future improvement.

Several points were also raised in preventing any further recurrence. First, urgent needs were indicated for a close coordination between Government Administration and professional researchers in preparation of any similar events, and also for a prompt inter-departmental coordination of Government bodies in dealing with after disaster managements.

As for companies, urgent needs were emphasized for the strengthening of corporate responsibilities in chemical safety of the products and also for the training and education to incorporate these responsibilities into everyday practices. The legal gaps unrevealed in this disaster should be closed by the revision of law as soon as possible, and especially specific needs were raised for a thorough review and reflect of technical details in this revision.

In order to never repeat a similar event of tragic damages due to chemicals or household products like humidifier disinfectants, all concerned parties of Parliament, Government, Business, Citizens, Professionals, and Media should take the lesson of this tragedy to their hearts.