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# ADHD labeling and treatment of children in Japan



CITIZENS COMMISSION ON HUMAN RIGHTS JAPAN  
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## Introduction

Children in Japan are being labeled with the psychiatric diagnosis attention-deficit/hyperactivity disorder (ADHD) and given psychiatric drugs in order to control the symptoms labeled as ADHD, just as in many European and American countries. The rate of the drugs used are different than those in Europe and the USA which is caused mainly by earlier abuses of psychostimulant drugs causing some of these to be banned and secondly a zero tolerance to drugs use in general (the psychostimulants used in the control of ADHD labeled children are actual drugs with a high abuse potential).

Large international pharmaceuticals are increasingly focusing on releasing new types of drugs on the Japanese market that can be prescribed to children labelled with ADHD such as lisdexamfetamine and guanfacine (sold under the name Intuniv). The Japanese market is being described as “the world’s third-biggest market for ADHD treatments” and is growing at more than 20 percent annually.<sup>1</sup>

Japanese children in early studies were found to be among those less considered fulfilling the diagnostic criteria for attention-deficit/hyperactivity disorder (ADHD).

Yet, marketing efforts and American psychiatrists have promoted the American concept of various behavioural symptoms clustered together and called ADHD, to a degree, that a large number of parents have taken on the concept. In recent years normal children, who sometimes may behave “unnormal” are being noticed as suffering from the symptoms which are called “ADHD” by their parents.

A study of preschool children in Niigata City, Japan exemplify this. A questionnaire survey conducted in Niigata City in 2003, involved an evaluation of ADHD symptoms by their school teachers. A second survey, conducted in 2006, involved an evaluation of the symptoms by parents in the same city. The teacher survey included 9.956 children, and the parent survey included 7.566 children. Parents and teachers assessed ADHD symptoms in children using a 14-item questionnaire based on the American Psychiatric Association’s diagnostic manual DSM-III-R. The parent survey showed that 31.1% of the parents believed their child had ADHD while the teachers believed it was 4.3% of the children.<sup>2</sup>

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<sup>1</sup> Shire, Shionogi's ADHD drug for adults clears late-stage trial in Japan; Reuters Health News – Staff reporting by Sam Nussey, editing by Edwina Gibbs; 20 Sept 2017.

<sup>2</sup> Environ Health Prev Med., Mar 2009; 14(2): 150–154. doi: 10.1007/s12199-008-0075-4. Prevalence of attention-deficit/hyperactivity disorder (ADHD) symptoms in preschool children: discrepancy between parent and teacher evaluations. By Yukio Soma, Kazutoshi Nakamura, Mari Oyama, Yasuo Tsuchiya, and Masaharu Yamamoto, Department of Community Preventive Medicine, Niigata University Graduate School of Medical and Dental Sciences.



The study concluded that “the large difference between the estimated prevalence of ADHD symptoms in Japanese preschool children from teacher and parent surveys suggests that compared to teachers, parents consider their children’s symptoms much more serious. Thus, parental evaluation of ADHD symptoms using DSM criteria may be inappropriate for ADHD screening.”

Yet, the more important question is what made these parents believe their own child behaved unnormal to a degree that their opinion would label nearly 1/3 of them with a psychiatric disorder. A disorder which symptoms in Japanese children at the same time were found to be among the lowest in the world.<sup>3</sup>

Such misconceptions could result in harm, including unjustified drugging with psychotropic drugs. This has to be seen in view of a 2003 survey which found that most Japanese doctors initiated drug treatment for ADHD at a very low threshold of symptoms found. It was found that psychotropic drugs were often used to “quell nuisances caused by children with ADHD, such as disturbing classes, breaking rules, or fighting, instead of improving hardwired difficulties in children with ADHD, such as attention deficit or lower academic performance.”<sup>4</sup>

The diagnosis of ADHD, is not based on actual medical tests or identifiable malfunctions in the body, but is entirely a subjective interpretation of the severity of a number of identified behavioral traits which are considered symptoms of the disorder. Some of these specific behavioural pattern are seen as unwanted. In Japanese culture, it is important to respect other people’s personal space. When a child is behaving very actively/impulsive or “interrupts and intrudes on others” (which is one of the defining symptoms of ADHD), this may be seen as very unwanted. The parents of a child who so behaves are often very concerned about this, because it breaks the cultural norm. As such, parents of a child with this symptom may be more inclined to getting their child diagnosed with ADHD, and they would be more inclined to give their child a drug to stop this behaviour.

In consequence new guidelines for ADHD treatment were formulated in 2003 stressing that parents, doctors, and teachers should keep in mind that in the case psychotropic drugs are to be used they have to be “administered on behalf of

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<sup>3</sup> “The main finding was that the variation in prevalence of ADHD.... The North American rate (6.2%) only slightly exceeded the European rate (4.6%). The highest rates emerged from Africa (8.5%) and South America (11.8%). Corroboration comes from a dimensional ADHD scale used in 21 countries. Japanese and Finnish children scored lowest, Jamaican and Thai children scored highest.” - *Am J Psychiatry*. 2007 Jun; 146(6): 856–858. doi: 10.1176/appi.ajp.164.6.856; Why does the worldwide prevalence of childhood attention deficit hyperactivity disorder matter? By Terrie Moffitt and Maria Melchior; Social, Genetic and Developmental Psychiatry Centre King's College, University of London, Institute of psychiatry, London, GB.

<sup>4</sup> Kanbayashi Y, Saito K, Kita M: Japanese Guideline for Diagnosis and Treatment of AD/HD [in Japanese]. Tokyo: Jiho; 2003.



children with ADHD and not on behalf of those around them.”<sup>5</sup> These guidelines were changed in 2006, and again in the FY2014 to FY2016.

American psychiatric studies nevertheless note that “in Japan, treatment with medication for attention-deficit/hyperactivity disorder (ADHD) is less favorable than psychosocial treatment, as in Europe.”<sup>6</sup> And “In many countries, the current mainstay of ADHD-related psychopharmacotherapy involves psychostimulants, despite recent abuse issues with Ritalin (Novartis, Basel, Switzerland). In Japan, amphetamine-type stimulants that are available in other countries are treated as narcotics; their manufacture, storage, and use are strictly prohibited by the Stimulant Drugs Control Law enacted in 1951.” It is noted that “only one stimulant (long-acting methylphenidate) is now available in Japan.”<sup>7</sup>

## Psychostimulant drugs use in Japan

After being widely used by the Japanese military and their allies through WWII, all stimulants were banned by the Japanese government in 1951. This occurred as a consequence of finding that they were strongly addictive. Since then, a zero-tolerance drug policy has since been instilled on many of the psychostimulants such as amphetamine by the Health, Labor, and Welfare Ministry.

In 1961, the psychostimulant drug methylphenidate (sold as Ritalin) was approved to treat depression and depressive neurosis. In those days, regulation by the Japanese government was not as strict as it is today.<sup>8</sup>

After methylphenidate became available in Japan, cases of abuse were soon reported. In 1973, a warning that “methylphenidate should be given cautiously because of a possible risk for dependency” appeared in the drug information.

In the 1960s, the first psychiatric clinical trials of methylphenidate, as well as dextroamphetamine, were completed in the United States, claiming efficacy for hyperactivity, impulsivity, and moodiness. Following these American trials, to reconfirm its efficacy for the Japanese population, uncontrolled trials of methylphenidate for ADHD symptoms were performed by Japanese child psychiatrists. They subsequently demanded that ADHD should be added to the indication for methylphenidate use in Japan, which was rejected.<sup>9</sup>

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<sup>5</sup> Ditto.

<sup>6</sup> SpringerLink - Current Attention Disorders Reports, March 2009, Volume 1, Issue 1, pp 21 –28; Psychopharmacology for attention deficit/ hyperactivity disorder in Japan; by Toshinobu Takeda, MD, Ph.D., Center for Management of ADHD, Children’s Hospital of Philadelphia, Philadelphia, USA.

<sup>7</sup> Ditto.

<sup>8</sup> Ditto.

<sup>9</sup> Ditto.



In Japan, methylphenidate (Ritalin) was then prescribed for ADHD as an off-label use (following a medical judgement not in accordance with the official approval) until 2007, when it was prohibited for ADHD treatment.

Cases with methylphenidate addiction or dependency have been found in Japan since the 1980s. Largely thanks to the Internet, an increasing number of methylphenidate addiction cases have been identified.

Almost all reported cases of methylphenidate abuse were triggered by prescriptions from medical facilities intending to improve depressive states. The cases further revealed that psychological dependence of methylphenidate was a rapid effect and that it easily became severe.

Some warnings against methylphenidate abuse/dependence were published in the pursuing time; some reported that methylphenidate abusers/dependents in search of large quantities of Ritalin visited multiple psychiatric clinics, feigned psychiatric disorders, and even falsified prescriptions using color copiers.

In 2007, prescribed Ritalin for inappropriate cases became a public concern when it was uncovered by a major Japanese newspaper – The Yomiuri – that, without proper medical examination, a clinic in Tokyo prescribed massive doses of Ritalin to probable Ritalin abusers/dependents.

In October 2007, the Ritalin indication was limited to narcolepsy only. Subsequently, the Ritalin Distribution Control Panel, a third-party organization, was established at the end of 2007. The panel decided that Ritalin must be prescribed by registered physicians only from registered pharmacies.

Shortly after in October the same year, it was decided that Concerta, another methylphenidate containing drug, may be prescribed for ADHD. The psychoactive substance in Concerta, which came on the market many years after Ritalin first was promoted, is released slowly which is claimed to decrease the abuse potential. This was the first time that a drug was officially approved for the treatment of ADHD. It may be used for children six years or older. Only registered psychiatrist or pediatrician who obtained a permission can prescribe this drug.

Ritalin sales have drastically plunged since distribution control began in early January 2008.<sup>10</sup>

In 2009 Strattera (Atomoxetine), a non-stimulant drug in the same drug classification group as methylphenidate, was approved for the management of ADHD symptoms.

In 2017 another non-stimulant drug Intuniv (Guanfacine) was approved for ADHD.

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<sup>10</sup> Ditto.

## Psychotropic drug use increasing for years

In the mid-2000s and more recently a growing number of Japanese children are being prescribed psychotropic drugs to treat attention deficit hyperactivity disorders (ADHD), according to a study by government-funded medical institutes.

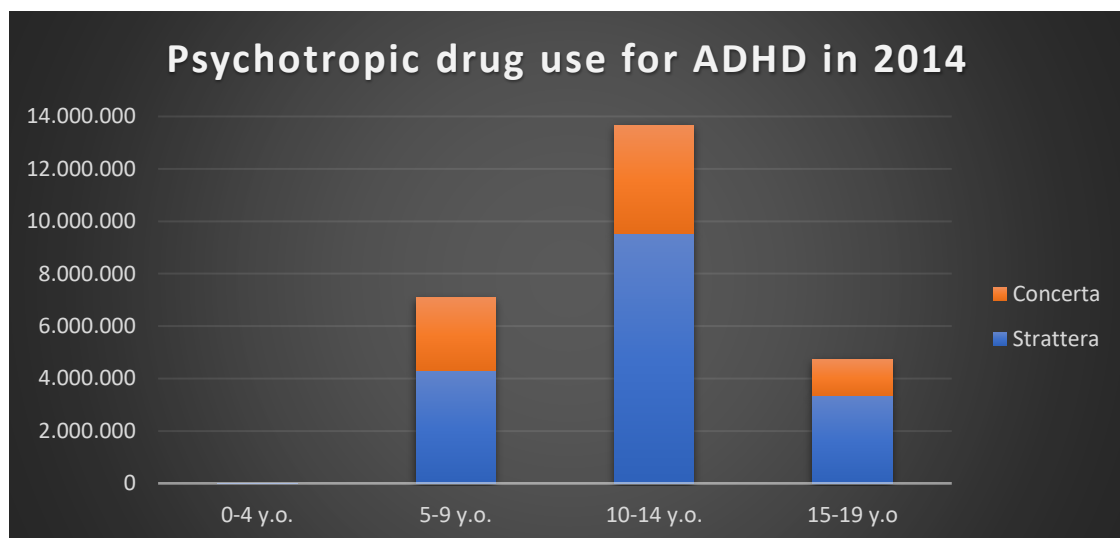
In particular, the number of ADHD drug prescriptions for patients aged 13 to 18 years old surged 2,49 times between two three-year periods covering 2002-2004 and 2008-2010. It was specifically noted this occurred despite some of them wasn't approved for use by children, the study said.<sup>11</sup>

“Frankly, this is an unfortunate situation for the medical community” because doctors have to take risks to provide some psychotropic drugs to underaged patients, said Yasuyuki Okumura, a researcher at the Institute for Health Economics and Policy and co-author of the research paper.<sup>12</sup>

The paper, which examined a total of 233,399 prescriptions issued by hospitals and clinics from 2002 to 2010, was published in November 2014 in the Japanese medical journal *Seishin Shinkeigaku Zasshi* (Journal for the Japanese Society of Psychiatry and Neurology).

Doctors in Japan dealing with children who are suffering from mental problems have long prescribed psychotropic drugs approved only for adults. They do this despite it is known doing so involves risks for the child. Okumura said that in Japan few clinical studies exist on psychotropic drugs for children, unlike in the U.S. and Europe, where clinical trials covering children are legally stipulated.

Fig. 1. Number of pills sold for the management of ADHD symptoms in Japan



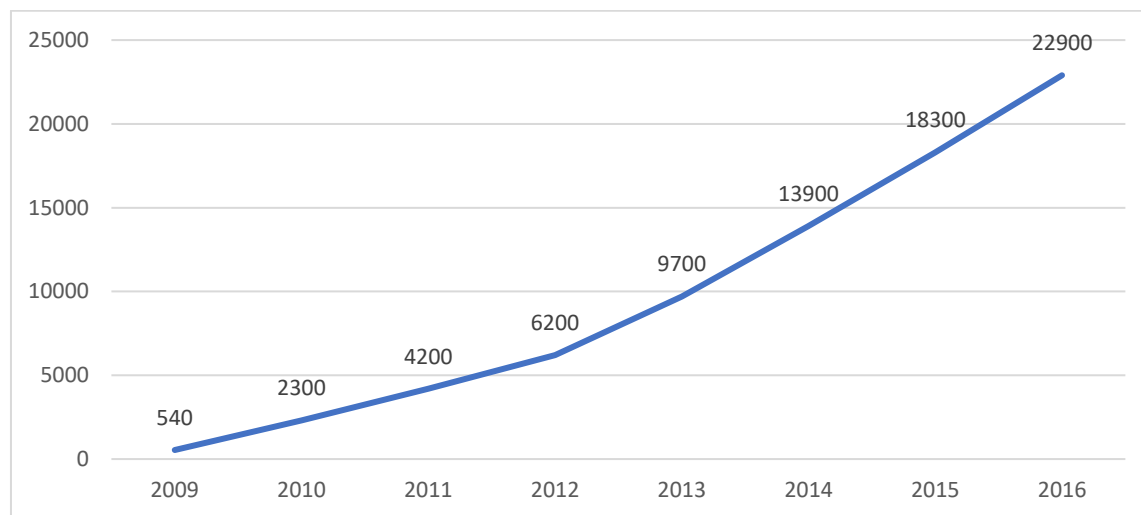
<sup>11</sup> More Japanese children being prescribed psychotropic drugs; The Japan Times, by Shusuke Murai - staff writer; 14 January 2015.

<sup>12</sup> Ditto.

Table. 1. Number of pills sold for the management of ADHD symptoms in Japan<sup>13</sup>

	0-4 y.o.	5-9 y.o.	10-14 y.o.	15-19 y.o.
Strattera	6.777	4.307.326	9.544.297	3.364.281
Concerta	0	2.766.744	4.125.325	1.366.601

Okumura and his team also found that the number of ADHD drug prescriptions for 6- to 12-year-old children during the years 2008-2010 increased 84 percent compared to the figure during 2002-2004.<sup>14</sup>

Fig. 2 Sale of Strattera (atomoxetine) in million Yen (JPY)<sup>15</sup>

## Pharmaceutical company lines to government

The international pharmaceutical company Shire – that is specifically targeting the ADHD market – has been looking to Japan to boost its growing ADHD drugs business. The Japanese market for ADHD treatments is growing at more than 20 percent annually, the company stated when it in September 2017 announced that its ADHD drug, Intuniv, sold by its Japanese partner Shionogi & Co Ltd had met its

<sup>13</sup> Source: NDB Open Data Japan. In 2009, the Ministry of Health, Labour and Welfare (MHLW) started operating the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB). The database accumulates health insurance claims every month and specific health checkup data every year, resulting in one of the most exhaustive healthcare database of a national size in the world. The first “NDB Open Data Japan” consists of fundamental spreadsheets that sum up the claim data of the fiscal year 2014 and the specific health checkup data of the fiscal year 2013. <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000177764.pdf>

<sup>14</sup> Ditto.

<sup>15</sup> Source: press releases of the pharmaceutical company Eli Lilly Japan K.K. which produce Strattera. [http://news.lilly.co.jp/news\\_list.html?page=1&category=7](http://news.lilly.co.jp/news_list.html?page=1&category=7)



main goal in a late-stage trial of adults in Japan.<sup>16</sup> The drug was already approved for children in Japan earlier in 2017.

The company with the expected release of two of its ADHD drugs to the Japanese market has built up a strong relationship with a number of governmental administrations. The Osaka Prefectural government (the second largest regional government in Japan) formed a partnership with Shionogi & Co., Ltd. about the field of enlightenment of developmental disorder on 25 January 2017.<sup>17</sup>

The Osaka Prefectural government further carried out a special event entitled “Symposium for developmental disorders: World Autism Awareness Day in OSAKA 2017” with Shionogi on 7 April 2017.<sup>18</sup>

Shionogi while working on these events obtained the manufacturing and marketing approval from the Japanese Ministry of Health, Labor and Welfare for their pediatric ADHD drug Intuniv® tablets (1 mg/3 mg) on 30 March 2017.<sup>19</sup>

Shionogi has also applied for approval to manufacture and sell the drug “lisdexamfetamine mesilate” (sold as Vyvanse in many countries) on 13 April 2017.<sup>20</sup>

Another regional government, Shiga Prefectural government, is about to form a partnership with Shionogi.<sup>21</sup>

## State party periodic reports omit data

The CRC in consideration of the third periodic report of Japan (CRC/C/JPN/3) in June 2010 noted an increase of ADHD diagnoses and in view of this recommended in its Concluding observations (61.) **“that the State party monitor the trends in the numbers of ADHD diagnoses and ensure that research in this area is conducted independently of the pharmaceutical industry.”**

The State party acknowledged a need for monitoring the numbers of ADHD diagnoses, stating in its fourth and fifth period reports (CRC/C/JPN/4-5 of 1 November 2017) that (107.) “The number of ADHD patients is identified through patient research.” And the state party added that: “From FY2014 to FY2016, the

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<sup>16</sup> Shire, Shionogi's ADHD drug for adults clears late-stage trial in Japan; Reuters Health News – Staff reporting by Sam Nussey, editing by Edwina Gibbs; 20 Sept 2017.

<sup>17</sup> <http://www.pref.osaka.lg.jp/gyokaku/kohmin/shionogi.html>

<sup>18</sup> [http://www.pref.osaka.lg.jp/hodo/attach/hodo-26330\\_4.pdf](http://www.pref.osaka.lg.jp/hodo/attach/hodo-26330_4.pdf)

<sup>19</sup> [http://www.shionogi.co.jp/en/company/news/2017/pmrltj0000003ahh-att/e170330\\_1.pdf](http://www.shionogi.co.jp/en/company/news/2017/pmrltj0000003ahh-att/e170330_1.pdf)

<sup>20</sup> <http://www.shionogi.co.jp/en/company/news/2017/pmrltj0000003b16-att/e170413.pdf>

<sup>21</sup> Chunichi Newspaper web news of 19 December 2017, <http://www.chunichi.co.jp/article/shiga/20171219/CK2017121902000003.html>

government created a medication guideline for children and adolescents with disorders, including developmental disorders."

The state party of Japan further provided some statistical information among others that the number of children with ADHD who are enrolled in special instruction in resource rooms (elementary and junior high schools) is 16,886.

The state party in other words is monitoring at least one part of the children being labeled with ADHD, but it does not comment or report on children being treated mainly with psychotropic drugs. The state party further does not report on the research and measures related to the handling of these children including the writing of the new guidelines were done "independently of the pharmaceutical industry."

## Guidelines written by professionals with financial ties to the pharmaceutical industry

The reason for this omission of the state party is most likely because this wasn't the case. The guideline was formulated by well-known psychiatrists of which most have financial ties with the pharmaceutical industry.

To exemplify this, is the case of Dr. Hironobu Ichikawa who was the president of the Japanese Society of ADHD (April 2010 to March 2016). He was also a special adviser to the Tokyo Metropolitan Children's Medical Center and president of Japan's Developmental Disorders Network (the biggest developmental disorders' group). While holding these positions Dr. Ichikawa did not report on getting money from pharmaceutical companies. This eventually became the subject of an exposure when an investigation was carried out by the Tokyo Metropolitan assembly on 9 March 2016.

According to an article in the Asahi Newspaper (10 March 2016), Dr. Hironobu Ichikawa got about 7 million Yen from two pharmaceutical companies in FY2013 to FY2014. The companies were Eli Lilly Japan K.K. and Janssen Pharmaceutical K.K. which are both selling ADHD drugs. Not revealing this is a violation of the applicable conflict of interest regulations.

Dr. Hironobu Ichikawa was one of the authors of the treatment guideline for children and adolescents with disorders, including developmental disorders written in FY2014. He mentioned the result of ADHD drug therapy in Tokyo Metropolitan Children's Medical Center in his contributions to the guidelines.

This guideline was made possible by a research grant provided by the Health and Labour Sciences. Any researchers and organizations receiving Health and Labour Sciences Research Grants have to declare their conflicts of interests. When the Ministry of Health, Labour and Welfare accepted the contribution of Dr. Ichikawa as a part of the guideline in FY2014, it considered there was no problem.

And the state party of Japan even mentioned this very guideline to the CRC as an argument that actions are taken: “From FY2014 to FY2016, the government created a medication guideline for children and adolescents with disorders, including developmental disorders.” The state party however omitted stating that the majority of the psychiatrists who formulated these guidelines including Dr. Hironobu Ichikawa were having published financial ties to the pharmaceutical industry.

It is not only individual ADHD researchers, experts and government advisors who are having financial ties to the pharmaceutical industry. The Japanese Society of ADHD is the expert medical association in the field of research of ADHD. This group has also been sponsored by the aforementioned two pharmaceutical companies. Eli Lilly Japan K.K. (which is the company selling the drug Strattera) sponsored the Society of ADHD with a total of 2,000,000 JPY in 2013 and 9,904,762 yen in 2014. Janssen Pharmaceutical K.K. (the company which are selling Concerta) sponsored the Society of ADHD with 1,500,000 yen in 2013 and 3,500,000 yen in 2014. The later years has not yet been publicized.

## Recommendations

CCHR is of the belief that in accordance with the Convention of the rights of the child’s articles 3, 4, 5, 6, 18 (3), 23-24, 27 (1)-(3) and 33, and the General Comments 5 (2003), 4 (2003), and 13 (2013) and as exemplified in other countries, that the state should:

Ensure that the diagnosis of children for ADHD and other similar diagnoses is done based on evidence of the disorder and in the best interest of that child, that research on the root causes of such disorders is carried out, and the recommended treatment is based on these findings of that child, that psychotropic drugs are prescribed as a measure of last resort and only after an individualized assessment of the best interests of the child, that children and their parents are properly informed about the possible side effects of medical



treatments and about non-medical alternatives, and that support is provided to initiatives aimed at the development of non-medical treatments for such disorders.

The state party further should ensure that experts and others advising or consulted in the process of implementing treatment and formulating guidelines are not having conflicts of interest and are independent of the pharmaceutical industry.

The current guidelines should be reviewed by independent experts. And the process is to be transparent.

## Citizens Commission on Human Rights

The Citizens Commission on Human Rights (CCHR) was established in 1969 by the Church of Scientology and co-founded by professor of psychiatry, Dr. Thomas Szasz to investigate and expose psychiatric violations of human rights, and to clean up the field of mental healing.

While CCHR doesn't provide medical or legal advice, it works closely with and supports medical doctors and medical practice. A key CCHR focus is psychiatry's fraudulent use of subjective "diagnoses" that lack any scientific or medical merit, but which are used to reap financial benefits in the billions, mostly from the taxpayers or insurance carriers. Based on these false diagnoses, psychiatrists justify and prescribe life-damaging treatments, including mind-altering drugs, which mask a person's underlying difficulties and prevent his or her recovery.

CCHR endorses the Convention on the Rights of the Child and specifically have been campaigning for the rights of the child throughout the world for more than a decade in which CCHR is active as an NGO.

Today, CCHR has more than 140 chapters in over 31 countries. Its board of advisers, called Commissioners, includes doctors, lawyers, educators, artists, businessmen, and civil and human rights representatives.

Noriyasu Yoneda  
CCHR Japan

Torsten Hjelmar  
CCHR Europe