THE MISREPRESENTATION OF ADHD & THE VIOLATION OF THE PUBLIC'S RIGHT TO INFORMED CONSENT

Admissions of the NIMH, APA, the FDA, Health Canada, and Others

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Information Systems Analyst

Introduction – What This Case Alleges

The classification of ADHD as a "neurodevelopmental disease" by the American Psychiatric Association (APA) has convinced many that symptoms are due to well-validated neurotransmitter deficiencies. The belief that drugs address such "well-understood" bio-chemical deficits skews their risk/benefit ratio by creating the misimpression of a "neuroscience based" medical need to choose drugs over drug-free therapies.

The misrepresentation described has helped spread the conviction that although addictive stimulants may ruin lives over time as the DEA warns, they should safely have lasting benefits for those with the purported deficiencies. This unsubstantiated hypothesis has been promoted as a fact by vested interests to justify recommending controlled substances as lifetime treatments even to toddlers, causing people to overlook not only the abuse potential of these drugs but also the absence of unbiased studies confirming their long-term safety and benefits (1) (2) (3). Health professionals and the public have thus been persuaded to attempt to manage behavioral or academic problems or other challenges with potentially deadly drugs of abuse (4), or with non-stimulant ADHD drugs whose labels warn of increased suicide risk (5).

Investigating scientific reports, articles and communicating with regulatory agencies has uncovered psychiatry's actual inability to legitimately identify any organic cause for ADHD including any neurotransmitter deficiencies "requiring" the drugs marketed as boosting these deficiencies. This is demonstrated with statements from the National Institute of Mental Health (NIMH), the U.S. Food and Drug Administration (FDA), Health Canada (Canadian FDA), ironically APA itself and credible medical experts. These statements invalidate a large body of biased and confounded studies and conclusively demonstrate the misrepresentation of ADHD as a neurological brain disease to make risky drugs seem "necessary." This represents the violation of the public's right to informed consent, since countless people might never have agreed to use ADHD drugs or give them to their children if they'd known that they were never "diagnosed" with an objectively verified "brain disease."

This paper does not deny the reality of ADHD symptoms nor goes into the debate over whether the cause of inattention/hyperactivity is brain-based; we only demonstrate that an *unproven hypothesis* has been deliberately misrepresented as substantially validated to create false confidence in dangerous drugs developed by those who don't understand what causes hyperactivity/inattentiveness. This misrepresentation has been covering up the fact that the recommended drugs arbitrarily alter the brain's chemistry, producing often life-destroying long-term consequences as the DEA warns about.

In the absence of legitimate scientific findings supporting APA's decision to call ADHD a neurodevelopmental brain disease, we identify the organization's well-publicized commercial interests as its motivator. Such financial motives have been fueling the ADHD drug prescription

epidemic for decades and unethically misleading the masses to increase the pharmaceutical industry's profits.

Supporting Facts

In 2009, Marcia Angell, M.D., former Editor-in-Chief of the world's most influential general medical journal, The New England Journal of Medicine, came out with her book "The Truth About the Drug Companies: How They Deceive Us and What to Do About It" (6). Angell also made the public statement:

> It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine. (7)

In 2015, Angel's statement was backed up by Richard Horton, the editor in chief of world's second most influential general medical journal, The Lancet. Horton stated in an editorial:

> The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness. As one participant put it, "poor methods get results." … The apparent endemicity of bad research behaviour is alarming. (8)

This lawsuit reveals the extent to which the above statements are true for the case of ADHD medications.

The American Psychiatric Association (APA) is the world's largest and most influential psychiatric organization which defines all mental disorder diagnostic criteria used by psychiatrists in North America. In July 2012, APA published the "Consensus Report of the APA Work Group on Neuroimaging Markers of Psychiatric Disorders," which contains the following admission about the data from the studies claiming to have discovered the brain-based causes of ADHD symptoms using neuroimaging technology (the most state-of-the-art brain research technology to-date):

> … While these data are important advances that contribute to our understanding of the brain and behavior interactions underlying ADHD, there is no current neuroimaging biomarker for ADHD. The vast majority of neuroimaging studies to date demonstrate relative, quantitative differences between ADHD and TDC [typically-developing controls

> without psychopathology] participants that are neither sufficiently large nor specific enough to be useful on a case-by-case basis as a diagnostic or treatment biomarker (9).

This demonstrates the fact that bio-chemical deficiencies or organic abnormalities have never been legitimately identified to exist in the brains of ADHD sufferers. ADHD drugs are not really "necessary" to address confirmed biological deficits.

In March 2010, Professor Allen Frances, prior APA member and previous chair of the DSM-IV Task Force, published a much-talked-about article in the Los Angeles Times (10). This article contains the compelling statement:

> The incredible recent advances in neuroscience, molecular biology, and brain imaging… are still not relevant to the clinical practicalities of everyday psychiatric diagnosis. The clearest evidence supporting this disappointing fact is that not even one biological test is ready for inclusion in the criteria sets for DSM-V [latest version of the manual published by APA which lists all criteria for diagnosing mental disorders]. (10)

In the versions of APA's DSM prior to the DSM-IV, mental disorders were divided into two categories called 'functional disorders' and 'organic disorders' (11). Organic disorders referred to illnesses like delirium or dementia having identifiable biological causes, and 'functional disorders' (also called psychiatric disorders) referred to conditions such as ADHD symptoms, depression or anxiety having no known organic basis (11). But in 1994, the DSM-IV eliminated this distinction between organic and functional disorders by arbitrarily starting to call all mental conditions diseases. The DSM-IV attempted to justify this by falsely stating in its introduction that "a compelling literature documents that there is much 'physical' in 'mental' disorders and much 'mental' in 'physical' disorders" (12). But this is a blatant misrepresentation as this paper will continue to demonstrate. The organic or chemical causes of not only ADHD but all psychiatric (functional) disorders could so far never be legitimately identified.

In his long career, neurologist Dr. Fred Baughman has "testified widely about the absence of proof that any psychiatric [functional] disorders have been validated as objective abnormalities" (13). He points out that all changes to each version of the DSM's diagnostic criteria "were changes wrought by consensus, in committee" instead of being changes dictated by objective scientific discoveries (14). Many years later, this statement has been confirmed by experts such as Dr. Thomas Insel, the previous chair of the National Institute of Mental Health (NIMH). Insel confessed in April 2013 in an article he posted on NIMH's website, stating "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure" (15).

Board certified neurologist Dr. Fred Baughman explains (personal correspondence):

> If they are going to deliver a brain damaging dose of ECT to a patient, that may be OK if they have elicited true, voluntary informed consent. If they prescribe and have performed, a brain-destructive cingulotomy--psychosurgery for obsessive-compulsive

> disorder (OCD) or schizophrenia, that too, may be OK, if they have true, voluntary informed consent.
>
> If they prescribe addictive and otherwise brain-dysfunction causing psychotropic drugs such as Ritalin, Dexedrine, Cylert and Norpramin for ADHD, that too may be OK if they have elicited true, voluntary informed consent.
>
> If, however, the patients and parents, even parens patriae—judges acting as parent surrogates, were wrongly, deceptively told that what the "patient" had were "diseases" and "chemical imbalances" of the brain, skewing their view of the risk/benefit ratio, leading to acceptance of one or more potentially brain-damaging treatments, then, we would have a flawed informed consent tantamount to medical malpractice.

The absence of objective scientific methods confirming that ADHD is a neurological organic disease has been noted and pointed out by numerous experts such as Assistant Professor Joseph Johnson, PhD and Professor Robert Reid, PhD. Professor Reid is an esteemed researcher who has "published over 100 articles and book chapters as well as coauthored the ADHD Rating Scale–IV, which is now used in seven countries … He is a recipient of the Special Education Student Research Award from the American Educational Research Association and the Jeannie P. Baliles Child Mental Health Research Award from the Virginia Treatment Center for Children," and "serves on the editorial boards of five journals and actively reviews for a number of others" (16). Reid and Johnson have written in 2012:

> One argument against the reality of ADHD is the fact that there is no proven medical test to confirm or disconfirm the presence of ADHD. This statement is entirely true. There is no blood test or DNA test for ADHD. ADHD cannot be seen in an X ray. New imaging techniques such as position emission tomography or magnetic resonance imaging – techniques that are so powerful that they actually allow scientists to view brain activation – cannot see ADHD. Neither can other techniques that measure brain electrical activity such as electroncephalograms or evoked potential. In sum, there is no "gold standard" for the diagnosing of ADHD. (17)

Even though APA's consensus admitted in 2012 that "there is no current neuroimaging biomarker for ADHD" (9), nevertheless, one year later in May 2013, APA decided to move ADHD from the DSM's Disruptive Behavior Disorders section to its Neurodevelopmental Disorders section. "This change better reflects the way ADHD is currently conceptualized," writes Duke University Research Professor David Rabiner, Ph.D. (18). But such researchers as well as the public have been misled, as the following paragraphs continue to demonstrate with additional admissions from Insel as well as admissions from the FDA and Health Canada which demonstrate that APA's decision to categorize ADHD as a neurological disease was not based on legitimate new discoveries as most people assumed.

In his April 2013 article where former NIMH director Insel admits that the DSM's diagnostic criteria are based not on objective methods but only descriptions of symptoms, Insel also writes, "… symptoms alone rarely indicate the best choice of treatment … Patients with mental disorders deserve better" (15). Insel then announces that to improve the existing symptom-based mental disorder classification system of the DSM, the NIMH has "launched the Research Domain Criteria (RDoC) project to transform [symptom-based] diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system" (15). But then Insel confesses that the Research Domain Criteria (RDoC) project could not pan out, because:

> It became immediately clear that we cannot design a system based on biomarkers or cognitive performance because we lack the data. In this sense, RDoC is a framework for collecting the data needed for a new nosology [the science of classification of diseases]. But it is critical to realize that we cannot succeed if we use DSM categories as the "gold standard." The diagnostic system has to be based on the emerging research data, not on the current symptom-based categories. (15)

Thus, to get rid of the DSM's symptom-based mental disorder diagnostic criteria sets, experts of the NIMH have analyzed the vast amount of junk-science claiming to have "discovered" the physiological basis of psychiatric disorders, but this only led to the NIMH having to conclude that any of this data can still not be taken seriously. This means that APA moved ADHD to the Neurodevelopmental Disorders section in its latest DVM-V in May 2013 based on illegitimate findings. This occurred a few weeks before the NIMH definitively announced (in April 2013) that they had not been able to do away with or improve any of the DSM's symptom based diagnostic criteria sets.

The Research Domain Criteria (RDoC) project launched by NIMH in 2013 still does not contain any data to allow psychiatric conditions to be diagnosed with objective methods (19). In May 2017, the influential journal Psychiatric Times reported that "This point is true: RDoC is not intended for actual clinical use at the current time" (20).

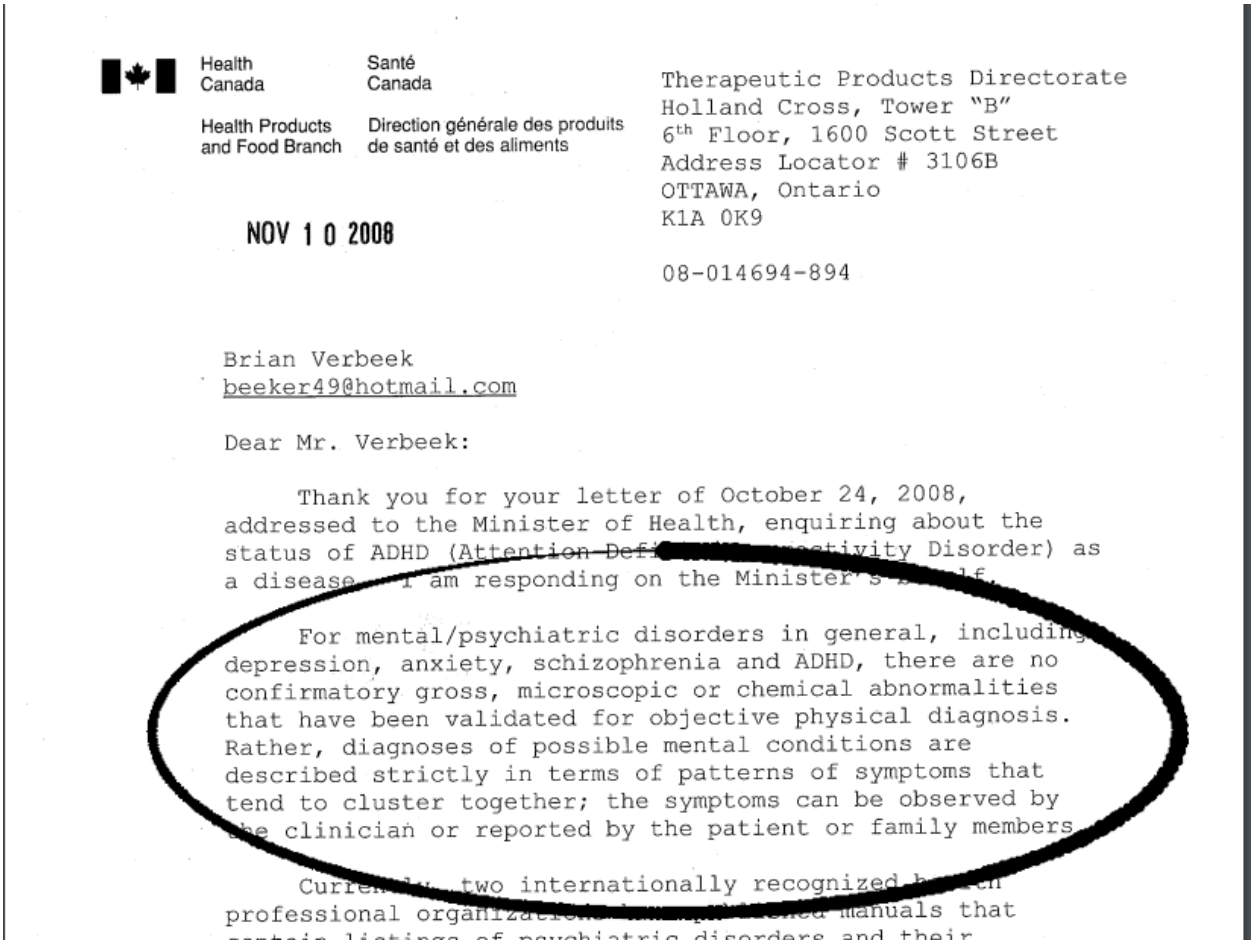
A concern that colleagues and friends have raised about all of this is the popular belief that serotonin deficiency causes depression and therefore the organic cause of this psychiatric condition must have been verified. But this is yet one more gross misrepresentation, as has been pointed out repeatedly by psychiatrists such as Dr. Daniel Carlat, author of the book "Unhinged: The Trouble with Psychiatry - A Doctor's Revelations about a Profession in Crisis." Carlat explains in an interview on NPR's "Fresh Air" (starts about 17:37 minutes into the interview):

> The problem is that we don't have any direct evidence that depression or anxiety or any psychiatric disorder is actually due to a deficiency in serotonin because it's very hard to actually measure serotonin from a living brain. And any efforts that have been made to

measure serotonin indirectly – such as measuring it in the spinal fluid or doing post-mortem studies – have been inconclusive. (21)

Going back to the case of ADHD, the unfortunate reality of the situation described has also been confirmed by personal communications with the U.S. and Canadian regulatory agencies of the pharmaceutical industry. The U.S. Food and Drug Administration (FDA) as well as Health Canada (Canadian FDA) have both repeatedly admitted that the organic or bio-chemical causes of psychiatric conditions have not been legitimately demonstrated. The following paragraphs first summarize the results of earlier communications with these agencies and then state what the FDA and Health Canada says in 2017.

In 2008, a patient of neurologist Dr. Baughman wrote a letter addressed to the Minister of Health of Canada, asking about the confirmation of ADHD as an organic disease. Director General of Health Canada responded on behalf of the Minister of Health, stating:



Health Canada / Santé Canada
Health Products and Food Branch / Direction générale des produits de santé et des aliments

Therapeutic Products Directorate
Holland Cross, Tower "B"
6th Floor, 1600 Scott Street
Address Locator # 3106B
OTTAWA, Ontario
K1A 0K9

NOV 1 0 2008

08-014694-894

Brian Verbeek
beeker49@hotmail.com

Dear Mr. Verbeek:

Thank you for your letter of October 24, 2008, addressed to the Minister of Health, enquiring about the status of ADHD (Attention Def[redacted]activity Disorder) as a disease. I am responding on the Minister's [redacted]lf.

For mental/psychiatric disorders in general, including depression, anxiety, schizophrenia and ADHD, there are no confirmatory gross, microscopic or chemical abnormalities that have been validated for objective physical diagnosis. Rather, diagnoses of possible mental conditions are described strictly in terms of patterns of symptoms that tend to cluster together; the symptoms can be observed by the clinician or reported by the patient or family members.

Currently, two internationally recognized health professional organizations [redacted] manuals that contain listings of psychiatric disorders and their

Dr. Baughman forwarded the above response to the FDA, asking them if they agreed with Health Canada stating that all mental/psychiatric disorders “have no confirmatory gross [macroscopic], microscopic or chemical abnormalities that have been validated for objective physical diagnosis.” The letter Dr. Baughman wrote the FDA asked them that if they disagreed with Health Canada, could they point out actual citations from the medical research literature demonstrating the organic or chemical causes of psychiatric (functional) disorders? Dr. Baughman wrote to the acting commissioner of the FDA:

Dear Dr. von Eschenbach,

I testified at FDA hearings of 3/22/06 and 3/23/06 on ADHD and addictive, Schedule II psychostimulants used to treat it.

Throughout psychiatry, including deliberations at the FDA, ADHD and all "mental illnesses" are considered to be actual diseases when making risk (of disease) vs. benefit (of medication) estimations. In psychiatry/mental health, potent medications are often used assuming the benefits (of the medication) outweigh risks (of the disease). Without objective proof of a disease, patient-by-patient, or in research subject-by-research subject, how can risk vs. benefit assessments be made? In fact, they can never be valid.
What proof is there that (1) ADHD, (2) bipolar disorder, (3) conduct disorder, (4) oppositional-defiant disorder, (5) schizophrenia, or, any psychiatric entry in the DSM-IV-TR, is an actual disease (with objective abnormality—gross, microscopic or chemical = disease, and no abnormality = normal = no disease)?

Please provide me with the reference-citation from the medical-scientific literature that ADHD is an actual disease with a confirmatory gross, microscopic or chemical abnormality. For example:

1. **Maple Syrup Urine Disease. Menkes JH, Hurst PL, and Craig JM. A new syndrome: Progressive familial infantile cerebral dysfunction associated with an unusual urinary substance, Pediatrics 14: 462, 1954.**
2. **Beutler, E, et al. A new genetic abnormality resulting in galactose-phosphate uridyl transferase deficiency, Lancet 1:353, 1965;**
3. **Baughman, F. A., Jr., List, C. F., Williams, J. R., Muldoon, J. P., Segarra, J. M.: The Glioma-Polyposis Syndrome. New England Journal of Medicine, 281:1345-1346, 1969.**

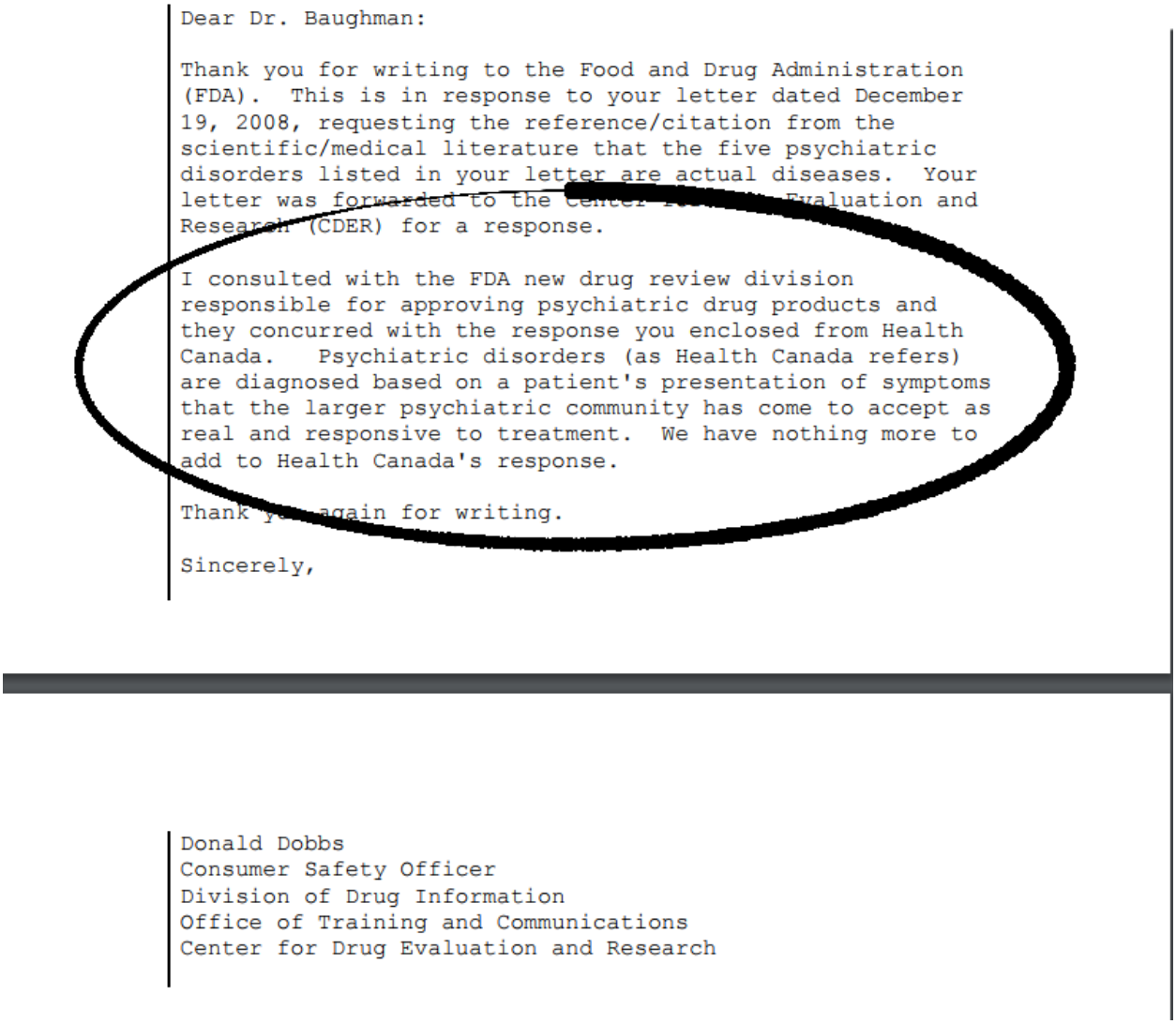
This is how medical-scientific communication is carried out. The diagnosis and treatment of all such psychiatric entities was recently assured by the passage of "parity" legislation. Are they on a par with non-psychiatric medical practice? Are they actual dise[illegible] the patients, parents and the public- at-large is told?

Again, I am asking for *nothing but* the reference/citation to the initial, one-and-only, scientific report which constitutes proof that (1) ADHD, (2) bipolar disorder, (3) conduct disorder, (4) oppositional-defiant disorder, or (5) schizophrenia, is an actual disease (with objective abnormality = disease, and no abnormality = normal = no disease).

Truly yours,

Fred A. Baughman Jr., MD

The acting commissioner of the FDA forwarded Dr. Baughman's letter and Health Canada's 2008 response to the FDA's Center for Drug Evaluation and Research. The head of this department replied to Dr. Baughman in March 2009, stating:



Dear Dr. Baughman:

Thank you for writing to the Food and Drug Administration (FDA). This is in response to your letter dated December 19, 2008, requesting the reference/citation from the scientific/medical literature that the five psychiatric disorders listed in your letter are actual diseases. Your letter was forwarded to the Center for Drug Evaluation and Research (CDER) for a response.

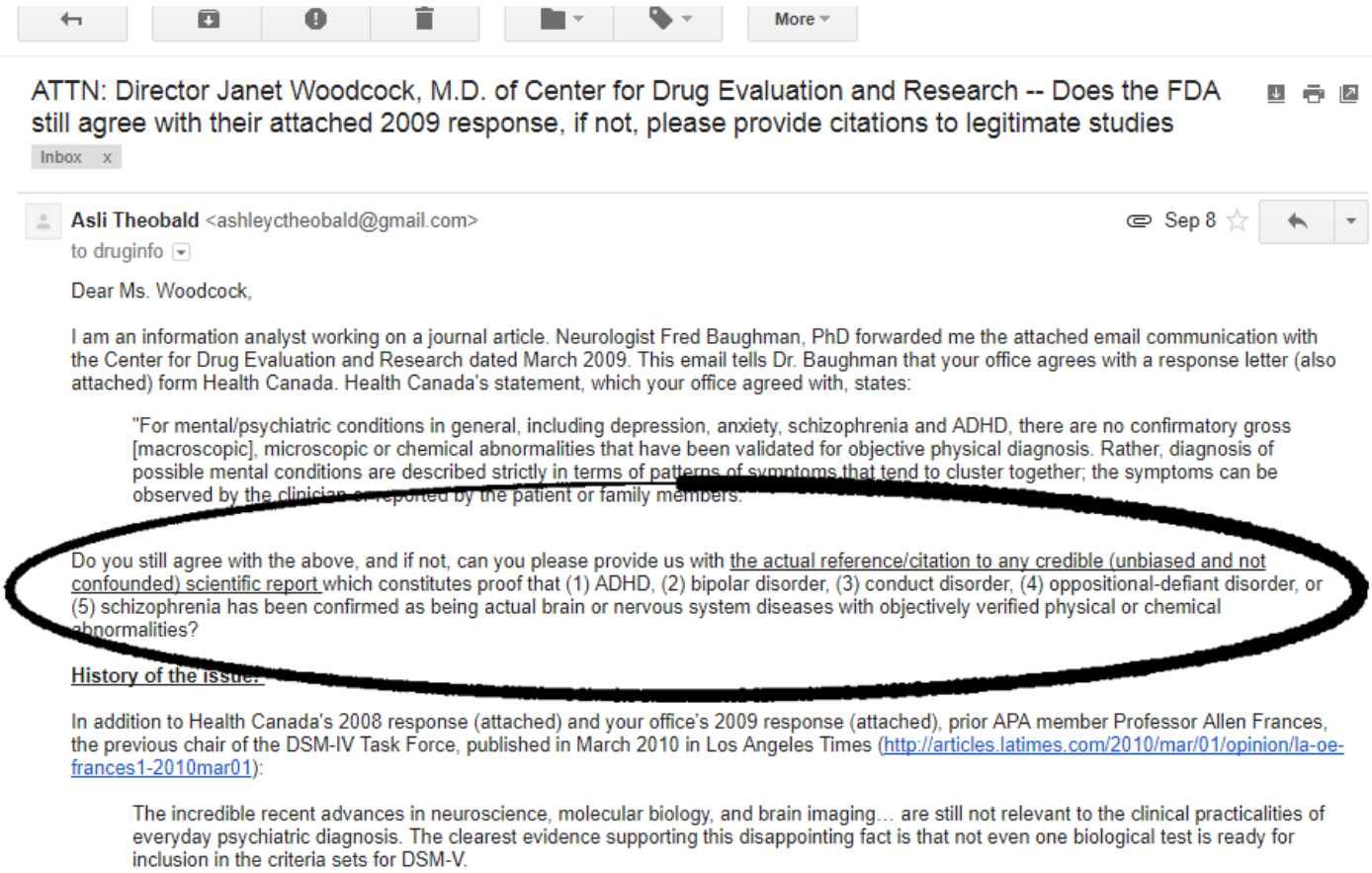
I consulted with the FDA new drug review division responsible for approving psychiatric drug products and they concurred with the response you enclosed from Health Canada. Psychiatric disorders (as Health Canada refers) are diagnosed based on a patient's presentation of symptoms that the larger psychiatric community has come to accept as real and responsive to treatment. We have nothing more to add to Health Canada's response.

Thank you again for writing.

Sincerely,

Donald Dobbs
Consumer Safety Officer
Division of Drug Information
Office of Training and Communications
Center for Drug Evaluation and Research

Wondering if the FDA still agrees with the above, on September 8th 2017, I contacted by email the current director of the FDA's Center for Drug Evaluation and Research (CDER). I quoted Health Canada's 2008 response and attached the FDA's own 2009 response agreeing with it. I asked CDER that if they have changed their minds about their 2009 statement, could they cite any credible, legitimate, unbiased and unconfounded studies supporting their new point of view. I wrote:



More

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ATTN: Director Janet Woodcock, M.D. of Center for Drug Evaluation and Research -- Does the FDA still agree with their attached 2009 response, if not, please provide citations to legitimate studies

Inbox x

Asli Theobald <ashleyctheobald@gmail.com> Sep 8

to druginfo

Dear Ms. Woodcock,

I am an information analyst working on a journal article. Neurologist Fred Baughman, PhD forwarded me the attached email communication with the Center for Drug Evaluation and Research dated March 2009. This email tells Dr. Baughman that your office agrees with a response letter (also attached) form Health Canada. Health Canada's statement, which your office agreed with, states:

> "For mental/psychiatric conditions in general, including depression, anxiety, schizophrenia and ADHD, there are no confirmatory gross [macroscopic], microscopic or chemical abnormalities that have been validated for objective physical diagnosis. Rather, diagnosis of possible mental conditions are described strictly in terms of patterns of symptoms that tend to cluster together; the symptoms can be observed by the clinician or reported by the patient or family members."

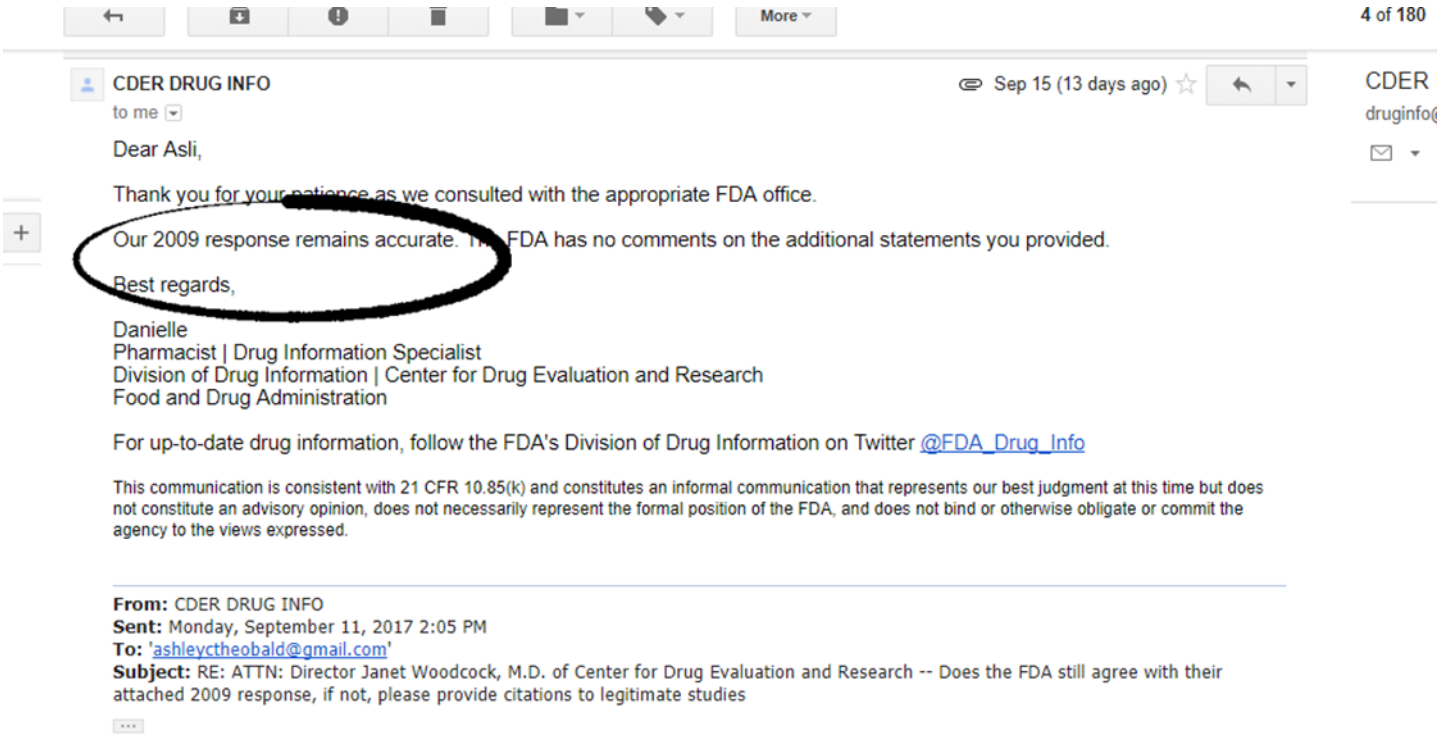
Do you still agree with the above, and if not, can you please provide us with the actual reference/citation to any credible (unbiased and not confounded) scientific report which constitutes proof that (1) ADHD, (2) bipolar disorder, (3) conduct disorder, (4) oppositional-defiant disorder, or (5) schizophrenia has been confirmed as being actual brain or nervous system diseases with objectively verified physical or chemical abnormalities?

History of the issue:

In addition to Health Canada's 2008 response (attached) and your office's 2009 response (attached), prior APA member Professor Allen Frances, the previous chair of the DSM-IV Task Force, published in March 2010 in Los Angeles Times (http://articles.latimes.com/2010/mar/01/opinion/la-oe-frances1-2010mar01):

> The incredible recent advances in neuroscience, molecular biology, and brain imaging… are still not relevant to the clinical practicalities of everyday psychiatric diagnosis. The clearest evidence supporting this disappointing fact is that not even one biological test is ready for inclusion in the criteria sets for DSM-V.

On September 15th 2017, the FDA's Division of Drug Information | Center for Drug Evaluation and Research (CDER) replied without citing any unbiased and unconfounded studies legitimately demonstrating the organic or chemical causes of psychiatric (functional) disorders. CDER wrote back:



More

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CDER DRUG INFO

Sep 15 (13 days ago)

to me

CDER

druginfo(

Dear Asli,

Thank you for your patience as we consulted with the appropriate FDA office.

Our 2009 response remains accurate. The FDA has no comments on the additional statements you provided.

Best regards,

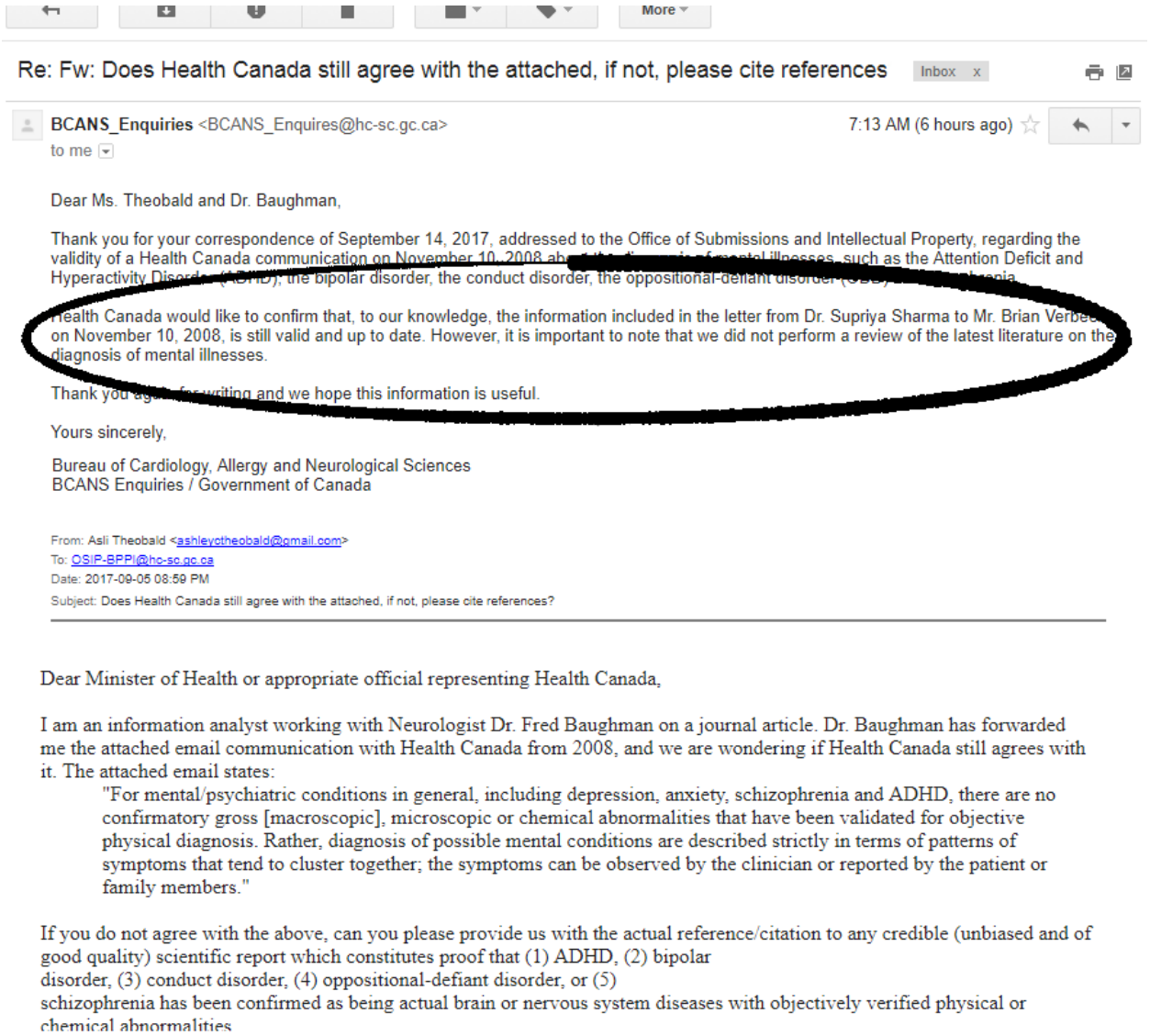
Danielle
Pharmacist | Drug Information Specialist
Division of Drug Information | Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter @FDA_Drug_Info

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: CDER DRUG INFO
Sent: Monday, September 11, 2017 2:05 PM
To: 'ashleyctheobald@gmail.com'
Subject: RE: ATTN: Director Janet Woodcock, M.D. of Center for Drug Evaluation and Research -- Does the FDA still agree with their attached 2009 response, if not, please provide citations to legitimate studies

I also asked Health Canada to confirm if their 2008 response is still accurate in 2017. On October 11th 2017, they replied:



Re: Fw: Does Health Canada still agree with the attached, if not, please cite references

Inbox x

BCANS_Enquiries <BCANS_Enquires@hc-sc.gc.ca> 7:13 AM (6 hours ago)

to me

Dear Ms. Theobald and Dr. Baughman,

Thank you for your correspondence of September 14, 2017, addressed to the Office of Submissions and Intellectual Property, regarding the validity of a Health Canada communication on November 10, 2008 about the diagnosis of mental illnesses, such as the Attention Deficit and Hyperactivity Disorder (ADHD), the bipolar disorder, the conduct disorder, the oppositional-defiant disorder (ODD), [redacted] schizophrenia.

Health Canada would like to confirm that, to our knowledge, the information included in the letter from Dr. Supriya Sharma to Mr. Brian Verbeek on November 10, 2008, is still valid and up to date. However, it is important to note that we did not perform a review of the latest literature on the diagnosis of mental illnesses.

Thank you again for writing and we hope this information is useful.

Yours sincerely,

Bureau of Cardiology, Allergy and Neurological Sciences
BCANS Enquiries / Government of Canada

From: Asli Theobald <ashleytheobald@gmail.com>
To: OSIP-BPPI@hc-sc.gc.ca
Date: 2017-09-05 08:59 PM
Subject: Does Health Canada still agree with the attached, if not, please cite references?

Dear Minister of Health or appropriate official representing Health Canada,

I am an information analyst working with Neurologist Dr. Fred Baughman on a journal article. Dr. Baughman has forwarded me the attached email communication with Health Canada from 2008, and we are wondering if Health Canada still agrees with it. The attached email states:

> "For mental/psychiatric conditions in general, including depression, anxiety, schizophrenia and ADHD, there are no confirmatory gross [macroscopic], microscopic or chemical abnormalities that have been validated for objective physical diagnosis. Rather, diagnosis of possible mental conditions are described strictly in terms of patterns of symptoms that tend to cluster together; the symptoms can be observed by the clinician or reported by the patient or family members."

If you do not agree with the above, can you please provide us with the actual reference/citation to any credible (unbiased and of good quality) scientific report which constitutes proof that (1) ADHD, (2) bipolar disorder, (3) conduct disorder, (4) oppositional-defiant disorder, or (5) schizophrenia has been confirmed as being actual brain or nervous system diseases with objectively verified physical or chemical abnormalities

These communications demonstrate that both the FDA and Health Canada dismiss the flawed studies supposedly supporting APA's 1994 statement claiming, "a compelling literature documents that there is much 'physical' in 'mental' disorders." Thus, APA seems to have deliberately misled the world when it started calling functional disorders diseases despite being aware that none of the junk-science it was promoting could be included in the mental disorder criteria sets they define. If the scientific literature contained any legitimate confirmation of the neurological cause of psychiatric conditions, wouldn't the drug manufacturers have pounced on these findings and have APA include them in their DSM as well as have the NIMH include them in its Research Domain Criteria (RDoC) project? The inability/refusal of APA, the NIMH, the FDA and Health Canada to draw attention to any specific study (despite our *persistent requests* that the regulatory agencies do so as our emails demonstrate) shows the absence of any admissible evidence demonstrating the organic causes of functional disorders including ADHD.

Neurologist Dr. Baughman strongly opposes referring to psychiatric conditions as "diseases", pointing out that the word disease serves to bias people "in favor of medical interventions, and against nonmedical interventions (e.g., love, will power, or talk therapy)" (13). Most people would be more inclined to assume that a "disease" must have physiological causes and should therefore not be able to go away with talk therapy or other non-medical approaches. This bias must be avoided, Dr. Baughman has persistently pointed out during his career, by keeping the definition of a disease limited only to objectively identified macroscopic, microscopic, or chemical abnormalities. We therefore ask the justice system to stop the calling of all functional disorders "diseases" based on the false premise that there is a "compelling" research literature justifying this. May the courts stop the perversion of science by vested interests claiming the existence of "brain diseases" based on the *hope* that objective diagnostic verification may someday become possible? Dr. Baughman quotes Arthur C. Clarke, scientific thinker and author of "2001: A Space Odyssey" who eloquently reminds us that the main goal of science is to remain objective instead of being shaped by personal wishes, biases, convictions, or assumptions:

> Science, unlike politics or diplomacy, does not depend on consensus or expediency—it progresses by open-minded probing, rigorous questioning, independent thought and, when the need arises, being bold enough to say that the emperor has no clothes (14).

Dr. Baughman adds:

> The American Psychiatric Association's Diagnostic and Statistical Manual has grown from 112 mental disorders in its initial, 1952 edition, to 163 in the 1968, DSM-II, to 224 in the 1980, DSM-III; 253 in the 1987, DSM-III-R, and, 374 in the 1994, DSM-IV. That there is more to the explosion of psychiatric "diseases" than scientific *naiveté* is obvious. To the extent that such research and its dissemination abrogates informed consent and becomes standard practice; is it not fraud? That it is a joint psychiatric-pharmaceutical industry strategy is obvious. (14)

Proving Dr. Baughman correct, arbitrarily starting to call psychiatric disorders diseases in 1994 coincides with the passing of compromised insurance laws which have forced more and more psychiatrists to offer only drug-therapies. These compromised laws have gradually caused an increase in the reimbursement rates for brief medication-only visits to psychiatrists and a significant decrease in the reimbursement rates for longer talk therapy sessions. This has resulted in only 10.8% of psychiatrists continuing to provide talk therapy to all patients by 2004-2005, states a 2008 study (22). The authors of this study add that consistent with past findings, they "found a strong positive association between self-pay visits and psychotherapy delivery." The same paper cites a Practice Research Network study which reports that third-party reimbursement for one 45- to 50-minute outpatient psychotherapy session is 40.9% less than reimbursement for three 15-minute medication management visits (23). The situation has been covered by the New York Times which quotes psychiatrist Donald Levin, who explains how he's been forced to quit offering psychotherapy to his patients. Levin states:

> At first, all of us held steadfast, saying we spent years learning the craft of psychotherapy and weren't relinquishing it because of parsimonious policies by managed care … But one by one, we accepted that that craft was no longer economically viable. Most of us had kids in college. And to have your income reduced that dramatically was a shock to all of us. It took me at least five years to emotionally accept that I was never going back to doing what I did before and what I loved. (24)

Compromised insurance laws have not just forced psychiatrists to drug all who seek them out, but have also caused a steady decline in reimbursement rates to psychologists over the years, which "uniquely undervalues psychologists' services," emphasizes the American Psychological Association (25).

In 2013, the Washington Post published a front-page story entitled "How a secretive panel uses data that distorts doctors' pay" (26). This article reports that "Unknown to most, a single committee of the AMA [American Medical Association], the chief lobbying group for physicians, meets confidentially every year to come up with values for most of the services a doctor performs." The article describes the extent to which "the nation's system for estimating the value of a doctor's services, a critical piece of U.S. health-care economics, is fraught with inaccuracies that appear to be inflating the value of many procedures." The reporters quote Tom Scully, Medicare chief during the George W. Bush administration, who stated "What started as an advisory group has taken on a life of its own … The idea that $100 billion in federal spending is based on fixed prices that go through an industry trade association in a process that is not open to the public is pretty wild." (26)

All of this demonstrates financial incentive to deliberately create bias for favoring drug treatments over risk-free therapies, a situation obviously benefiting not patients but the industry. When APA published the DSM-IV in 1994 and started calling functional disorders "diseases," this highly compromised (27) (28) organization has helped the industry cover up the fact that psychiatry had begun pushing only drug treatments onto patients despite its utter failure to understand the bio-chemical causes of psychiatric conditions.

Would the countless people who have consented to using psychiatric drugs have done so if they'd known that psychiatry has no clue what its drugs do to their brains? Would they have agreed to use medications if they'd known that their psychiatrist had drugged them just so his own income would not diminish? Would people have consented to the altering of their own or their child's brain chemistry in unknown ways just to create temporary feel-good effects?

A lawsuit that Dr. Baughman filed in 2002 succeeded in causing the Brain Foundation of the Netherlands to stop misrepresenting ADHD as an inherent brain dysfunction. The Advertisement Code Commission of Holland agreed that to call ADHD a "brain disease" is misleading (29). But in the United States, allowing psychiatric conditions to be called "diseases" has deliberately and cleverly opened the door to then starting to call them "brain diseases" (if a psychiatric condition is a disease then it must be a disease of the brain), which has opened the

door to calling these conditions "neurological diseases" or "neurodevelopmental diseases" (if it's a brain disease then it's neurological). We therefore ask the justice system to follow Holland's example to stop the violation of the public's informed consent with all such misleading terminology. We request that in addition to reverting to calling psychiatric conditions functional conditions instead of "diseases," may these conditions also not be called "syndromes," as well as not being called "biologically based," "neurobiological," "neuro-psychiatric," "neurodevelopmental," or neuro-*anything*? Dr. Baughman adds that all mention of hyperactive/inattentive children as "diseased," "abnormal," or "patients" must also stop in the absence of objectively diagnosable macroscopic, microscopic or chemical abnormalities. Otherwise, as this paper will further demonstrate, science may only be expected to keep degenerating to build false confidence in risky drugs developed by those who *don't* understand the causes of psychiatric conditions.

Continuing with laying out the non-scientific motives behind fabricating unsubstantiated "neurological diseases," in 2005, the organization Essential Science Indicators reported that ADHD came to be recognized as a "brain disease" largely due to the efforts of one compromised researcher. Harvard professor Dr. Joseph Biederman has had the greatest success in spreading "the notion accepted today that ADHD is a treatable, serious brain disorder of genetic etiology," states the organization's report (30). This report explains:

> According to our Special Topics analysis of ADD/ADHD research over the past decade, the scientist with the most-cited research is Dr. Joseph Biederman, with 294 papers cited a total of 6,866 times to date. Dr. Biederman is a contributing author to five papers in this Topic's list of most-cited papers from the past decade and the past two years. (30)

While Biederman was busy misleading the medical community and the public, he repeatedly avoided disclosing most of the drug company contributions he received. But congressional investigations uncovered about $1.6 million dollars in personal payments from the drug manufacturers between 2000 and 2007, when Biederman only reported $200, 000 of this income to Harvard (28). Biederman did not only lie to his university but also to congress, reports the New York Times. Their article states:

> In one example, Dr. Biederman reported no income from Johnson & Johnson for 2001 in a disclosure report filed with the university. When asked by Senator Charles E. Grassley, an Iowa Republican who is leading the Congressional inquiry, to check again, Dr. Biederman said he had received $3,500. But Johnson & Johnson told Mr. Grassley that it paid $58,169 to Dr. Biederman in 2001. (31)

As the facts outlined in this paper demonstrate, Biederman was again lying when he told the New York Times that his interests were "solely in the advancement of medical treatment through rigorous and objective study" (31). Proving Biederman's words wrong, in 2009, the New York Times also obtained copies of the court documents of Biederman's interactions with

Johnson & Johnson. This revealed that in a slide, Biederman promised Johnson & Johnson, *in advance*, a favorable study to "extend to adolescents positive findings with Concerta in A.D.H.D. N.O.S. [atypical ADHD cases] in adults" (32). The promised positive findings seemed to come out in 2006 (32).

In a report by Thomson Reuters entitled "The World's Most Influential Scientific Minds 2015," Biederman comes fifth from the top in the category of the world's most influential psychiatrists (33). And so ADHD has come to be "recognized" as a "serious brain disease" of "genetic etiology."

The term key opinion leader (or shortly KOL) refers to influential experts who regularly accept from the drug manufacturers research funding and/or personal payments in the form of speaking fees, consulting fees or honoraria. As a 2008 article in the British Medical Journal (BMJ) reports, marketing drugs through such hired experts is so common that numerous independent firms have developed software-based solutions to help the pharmaceutical industry manage its countless key opinion leaders (34). The websites of such KOL management companies teem with funny sounding phrases. For example, Veeva Systems states that their software Veeva KOL Data allows "Improving key opinion leader engagement as healthcare evolves" (35). The same article explains that "Building lasting relationships requires navigating complex key opinion leader (KOL) networks, delivering highly specialized information, and deeply understanding KOLs' sentiments and attitudes." The website of another popular Key Opinion Leader management company, KOL Llc., states that their software helps perform "influence mapping" and to "identify rising stars," referring to physicians whose influence is on the rise (36). Genpact is yet another popular KOL management company, whose website describes how they help "Identify, profile, engage and monitor the right set of influencers for measurable business impact" (37).

Internet searches bring up numerous additional companies also offering key opinion leader management or advocacy development programs. These include OpenQ, CRMSolutions, Cravel Group, MedThinkConnect, SteepRock, Reltio, Truven Health Analytics, Steeprock Inc., Global Vision Technology, and the list goes on to indicate the widespread popularity of using drug company paid medical experts to increase the industry's profits. Such a frightening proliferation of KOL management companies demonstrates the extent to which the public and health professionals let themselves get influenced by a huge network of business intermediaries masquerading as experts. The key opinion leader management industry may continue to grow for as long as this compromised system allows such practices and permits the misleading of millions who still trust "expert knowledge."

The Internet teems with countless examples of misrepresentations stated by KOL's who may be marketing medications like Biederman while stuffing their wallets. Some of these physicians might be misled themselves and genuinely believe APA's misrepresentations and the findings of the confounded studies created and disseminated with drug company funds. For example, Dr. Larry Silver describes the so called "biology behind ADHD" in his article entitled "Neuroscience

101” (38). Here, Silver makes numerous false statements which may have helped persuade countless parents to prefer the use of dangerous ADHD drugs as a first line treatment to make their children temporarily pay more attention to their teachers or keep quiet. Silver states:

> ADHD was the first disorder found to be the result of a deficiency of a specific neurotransmitter — in this case, norepinephrine — and the first disorder found to respond to medications to correct this underlying deficiency. (38)

Dr. James Wiley, the creator of the popular blog FocusMD.com, also falsely states:

> Both diabetes and ADHD result from chemistry problems. In diabetes the pancreas slowly quits making insulin, the hormone that controls blood sugar. While in ADHD, the brain’s neurotransmitters (chemical messengers) like dopamine and norepinephrine, are under activated. (39)

Dr. Russell A. Barkley, an award-winning clinical professor of psychiatry and pediatrics at the Medical University of South Carolina, also “explains” the never-proven so called “neuroscience of ADHD” in his “Complete, Authoritative Guide for Parents,” misleading millions by falsely claiming that “… stimulants are no different from using insulin for a child with diabetes” (40). Such bestsellers authored by ADHD mavens continue to defraud the masses who trust them.

Another ADHD maven and bestselling author Dr. Edward Hallowell not only misleads the public but also seems to try to intimidate his peers by threatening them with ridicule if they oppose the consensus. Hallowell claims that to say ADHD does not exist is “like saying the world is flat” (41). Hallowell adds that “those days are over. Today we have brain scans, genetic studies, twin studies that show that this is a highly inherited neurobiological disorder, not some made-up condition.” But neither the FDA nor the National Institute of Mental Health (NIMH) nor Health Canada have been persuaded to take this junk science that Hallowell promotes seriously as has been demonstrated. The NIMH’s former director Dr. Insel further emphasizes that “despite high expectations, neither genomics nor imaging has yet impacted the diagnosis or treatment of the 45 million Americans with serious or moderate mental illness each year” (42).

In a profession which has let false claims by vested interests replace objective methods, we have seen that psychiatry has first created an ever-increasing number of “diseases,” followed by successfully turning one of them into a “neurodevelopmental disease.” To be able to garner similar perceived credibility onto all psychiatric “diseases,” influential key opinion leaders have recently been promoting having psychiatry merge with neurology (43). As this issue is currently being debated, time will tell if the clothing of the emperor will be completed by totally blurring the line separating objective science from unproven assumptions popularized for profit.

The latest “ADHD Medication Manufacturing: Market Research Report” of IBISWorld states that “In the five years to 2021, industry revenue will continue to grow as the trends from the previous five years bolster utilization rates” (44). The healthcare system may keep deteriorating as predicted, unless the justice system may succeed at starting to clean it up. We therefore ask

that the courts restore the dignity of science by restoring its objectivity and criminally penalizing the managers &owners of the drug manufacturers below.

The Drug Companies Being Sued for Misrepresenting ADHD on Their Websites

In a country whose laws have been compromised so thoroughly, the ADHD drug manufacturers have not bothered to wait for psychiatry to be merged with neurology to start claiming that their psychiatric drugs treat "neurological diseases." The following paragraphs demonstrate the extent to which the ADHD drug manufacturers Shire, Eli Lilly, Janssen, and Novartis misinform health professionals and the public on their company websites, causing the violation of the informed consent of countless people who visit these sites or see the physicians misinformed.

Shire Pharmaceuticals manufactures the ADHD medications Adderall, Vyvanse and Daytrana. Their so called "ADHD Institute" created and funded by them (stated in almost illegible tiny print in their website header) has a webpage entitled 'NEUROBIOLOGY – ADHD is Associated with Structural, Functional and Neurotransmitter Alterations in the Brain' (45). Everyone who visits this webpage is fooled into believing the legitimacy of the colossal amount of junk science Shire promotes here as it "explains" the baseless "neurobiological basis" of ADHD.

Eli Lilly Pharmaceuticals, the manufacturer of Strattera for ADHD, has a webpage classifying the company's drugs by their therapeutic areas of use. (The site may ask you to first click "I am a Healthcare Professional Registered to Practice in the US" to let you view this page) (46). This webpage features buttons labeled CARDIOVASCULAR, DIABETES, ONCOLOGY, etc. as well as a button labeled NEUROSCIENCE, leading to Lily's associated drugs. If a health professional were to click the button labeled DIABETES or CARDIOVASCULAR, he would be appalled if he were to see drugs never legitimately demonstrated to help with diabetes or heart disease. But few health professionals realize that the button labeled NEUROSCIENCE brings up 4 of the company's most dangerous psychiatric drugs including Strattera for ADHD, all of which have never been legitimately demonstrated to help with any neurological disease of the brain or nervous system. All of these 4 psychiatric medications have FDA issued black box warnings (strictest possible FDA warning) on their labels cautioning of serious adverse reactions including increased suicide risk for children and adolescents and increased mortality in the elderly. The misrepresentation of such potentially deadly drugs fools health professionals into assuming that prescribing such drugs is justified for treating substantially validated organic neurological diseases. This false claim is repeated by Eli Lilly on another product page which again lists Strattera in the "Neuroscience" category (47).

Janssen Pharmaceuticals is a subsidiary of Johnson & Johnson which produces the popular ADHD drug Concerta. The company has a webpage entitled PRODUCTS, where health professionals and the public can view medications categorized by "Therapeutic Area" (48). Expanding the drop-down arrow under "FILTER RESULTS BY:" and selecting "Neuroscience" brings up all of Janssen's psychiatric drugs including Concerta. The word "Neuroscience" repeatedly appears on this page numerous times emphasized in bold letters each time next to every psychiatric medication including Concerta.

Novartis Pharmaceuticals, which produces the ADHD drugs Ritalin and Focalin, also lists ADHD under the subheading "Neuroscience" on its website (49), falsely including ADHD in this category along with legitimately confirmed neurological diseases such as multiple sclerosis, Alzheimer's disease, Parkinson's disease and epilepsy.

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