PsychRights®
Law Project for
Psychiatric Rights, Inc.

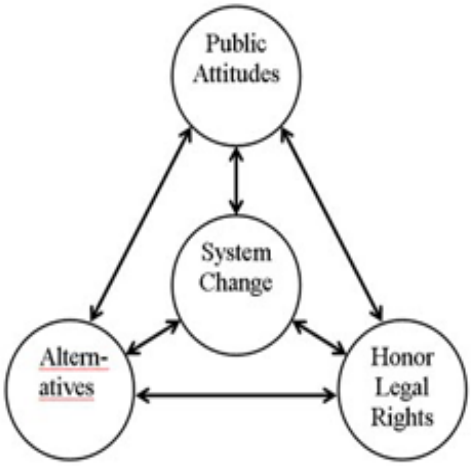
MEMORANDUM

TO: Aby Adams
FROM: James B. Gottstein, Esq.
RE: Potential Strategies
DATE: October 6, 2007

Introduction

You have asked me to provide "a brief summary of your legal strategy with some supporting material to distribute" at an upcoming training for attorneys" appointed to defend against involuntary commitment, forced drugging (ie., "Rogers Orders") and related proceedings.

As you know, the mission of the Law Project for Psychiatric Rights (PsychRights®) is to mount a serious, strategic litigation campaign against forced (court ordered) psychiatric drugging and electroshock around the country. PsychRights conceives of this in the context of the larger effort to reform the mental health system to one that promotes recovery, rather than create chronic illness, as it does now.[1] The graphic to the right depicts the three elements that reinforce each other, which PsychRights believes must be worked simultaneously to achieve meaningful change.[2]



This, memo, of course is directed at the "Honor Legal Rights" element, but it seemed worthwhile to put this into at least PsychRights' conceptual framework.

Purpose

I wrote a memo titled Opposing Forced Drugging ("Rogers Orders") in Massachusetts in February of 2004, which is an overview of PsychRights' understanding of the situation in Massachusetts at that time. The purpose of this memo is to suggest to two specific tactics to seriously challenge forced drugging under *Rogers*, 390 Mass. 489, 458 N.E.2d 308 (Mass.1983). These are (1) filing written testimony as to the "Best Interests," elements required in *Rogers* and (2) as part of this, subpoenaing the suppressed studies hiding data showing the drugs have very limited effectiveness and do great harm.

---

[1] *See*, attached forms of affidavits from Robert Whitaker and Ronald Bassman and transcript of testimony of Sarah Porter.

[2] The paper How the Legal System Can Help Create a Recovery Culture in Mental Health Systems describes this in some detail. http://psychrights.org/Education/Alternatives05/RoleofLitigation.pdf

Written Testimony on Best Interests

In *Rogers*, the Massachusetts Supreme Judicial Court held: "At least six factors must be considered by the judge in arriving at the substituted judgment decision,"[3] and then had a catch-all seventh. The ones relevant to the suggested strategy are:

4. The probability of adverse side effects.
5. The prognosis without treatment.
6. The prognosis with treatment.
7. Any other factors which appear relevant.

The problem is that forced drugging defendants normally have no meaningful way to challenge the hospital's script with respect to these elements, which can be grouped together under "best interests." The suggestion is to submit written testimony with the witness being available for cross-examination. This assumes these are non-jury cases. I've attached as Exhibits A & B, respectively, the form of affidavits I recently filed in a case in Alaska by Robert Whitaker and Ronald Bassman, respectively.[4] Both Mr. Whitaker and Mr. Bassman are willing to allow the submission of these same affidavits for a modest fee, say $100, and then be available for cross-examination on an hourly basis. Mr. Whitaker lives in Cambridge, while Dr. Bassman lives in upstate New York.[5] I have also attached, as Exhibit C, the in-court testimony of Sarah Porter as an illustration of some live less intrusive alternative testimony.

The Alaska testimony was focused on the Alaska Supreme Court ruling in *Myers v. Alaska Psychiatric Institute*, 138 P.3d 238, 454 (Alaska 2006) that:

> [A] court may not permit a treatment facility to administer psychotropic drugs unless the court makes findings that comply with all applicable statutory requirements and, in addition, expressly finds by clear and convincing evidence that the proposed treatment is in the patient's *best interests* and that *no less intrusive alternative is available*.[6]

The "best interests" requirement is similar to factors 4-6 of *Rogers*, but *Rogers* did not explicitly hold that no forced drugging order could be issued if there is a less intrusive alternative.[7] However, I think it is implicit and it certainly can be raised under the seventh factor required by *Rogers*, " Any other factors which appear relevant." Also, Factor 5, "The prognosis without

---

[3] 390 Mass at 505, 458 N.E.2d at 319.

[4] Most of the studies cited are available on PsychRights' website and I am pretty sure at least any missing from Whitaker's affidavit will be posted shortly. These are the full, published, articles, not just abstracts and thus are also available to be downloaded and attached to pleadings.

[5] Because of extremely remote locations in Alaska, telephonic testimony is routinely allowed, but it is recognized it might be much harder in Massachusetts, which would require the in-court availability of the witness(es). Dan Kriegman, a Boston area psychologist could almost certainly testify to the same effect as to both affidavits.

[6] 38 P.3d at 254, emphasis added.

[7] *Rogers* does hold there must not be any less intrusive alternative before the state may use its "police power" justification, 390 Mass at 510, 458 N.E.2d at 321, and it is hard to see why it wouldn't apply to the best interests (*parens patriae*) justification as well.

treatment" really should allow for alternative treatment. In addition, in *Guardianship of Roe*,[8] cited with approval in *Rogers*,[9] the Supreme Judicial Court of Massachusetts held "the intrusiveness of the proposed treatment" was a key factor. In other words, the availability of a less intrusive alternative is a key part of the best interests determination, even if it has not been explicitly recognized in Massachusetts.

The key suggestion is that written testimony regarding the *Rogers* (and *Roe*) factors should be submitted because otherwise no meaningful defense can be mounted against the stacked deck of the hospital's (or whoever's) psychiatrist testimony. Whether Whitaker or Bassman or Kriegman are used, or other people, the written testimony must be compelling and should be used in everyone's case.[10]

Finally, it is worth noting that the state's failure to fund a less intrusive alternative is no excuse for not providing such alternative. *Wyatt v. Stickney*, 344 F.Supp. 387, 392 (M.D.Ala.1972) ("no default can be justified by a want of operating funds."), affirmed, *Wyatt v. Anderholt*, 503 F.2d 1305, 1315 (5th Cir. 1974)(state legislature is not free to provide social service in a way that denies constitutional right). In *Wyatt* the federal courts required the State of Alabama to spend funds in specific ways to provide constitutionally adequate services.

Subpoenaing Suppressed Negative Data and Misleading Marketing Data on the Drugs

The manufacturers of all of the so-called "atypical" neuroleptics, such as Risperdal, Seroquel, Zyprexa and Abilify, only release studies that are arguably positive, while hiding all of the rest. In addition, they engage in a systematic marketing campaign to mislead doctors into prescribing these drugs when they shouldn't. The suggestion is to subpoena all of these suppressed studies as well as the marketing materials on the grounds that the court can not possibly properly engage in the required *Rogers* analysis without this information. A copy of the materials subpoenaed with respect to Risperdal (risperidone) in a case PsychRights has going here is attached as Exhibit D.[11]

Of course, the manufacturers will stone wall on providing the documents, but that is okay so long as the forced drugging is not allowed until the documents are produced.[12]

---

[8] 383 Mass. 415, 437, 421 N.E.2d 40, 53 (Mass. 1981)

[9] 390 Mass at 503, 458 N.E.2d at 317.

[10] This should be accompanied by aggressive lawyering to prevent the likely ignoring of this evidence by the trial court (or whoever is delegated to make the determination). Appeals must be pursued and stays of any orders authorizing forced drugging must be sought and pursued at various levels of appellate review to try and prevent the drugging in the interim. Resort to federal court for an injunction under 42 USC §1983 should even be considered.

[11] The hospital folded its tent on the forced drugging in the face of the challenge PsychRights made so the subpoenas issued for the suppressed data on Risperdal and other drugs became moot (we are now litigating its obligation to provide a less restrictive alternative instead of just discharging PsychRights' client without the sorts of support that gives him a good chance of doing much better).

[12] There is also the question of analyzing any documents that might be produced and PsychRights believes it will be able to get an appropriate expert(s) to do so.

AFFIDAVIT OF ROBERT WHITAKER

STATE OF MASSACHUSETTS)
) ss.
SUFFOLK COUNTY)

By Robert Whitaker

I. Personal Background

1. As a journalist, I have been writing about science and medicine, in a variety of forums, for about 20 years. My relevant experience is as follows:

a) From 1989 to 1994, I was the science and medical writer for the *Albany Times Union* in Albany, New York.

b) During 1992-1993, I was a fellow in the Knight Fellowship for Science Writers at the Massachusetts Institute of Technology.

c) From 1994-1995, I was director of publications at Harvard Medical School.

d) In 1994, I co-founded a publishing company, CenterWatch, that reported on the clinical development of new drugs. I directed the company's editorial operations until late 1998, when we sold the company. I continued to write freelance articles for the *Boston Globe* and various magazines during this period.

e) Articles that I wrote on the pharmaceutical industry and psychiatry for the *Boston Globe* and *Fortune* magazine won several national awards, including the George Polk Award for medical writing in 1999, and the National Association of Science Writers award for best magazine article that same year. A series I wrote for the *Boston Globe* on problems in psychiatric research was a finalist for the Pulitzer Prize in Public Service in 1999.

f) Since 1999, I have focused on writing books. My first book, *Mad in America*, reported on our country's treatment of the mentally ill throughout its history, and explored in particular why schizophrenia patients fare so much worse in the United States and other developed countries than in the poor countries of the world. The book was picked by *Discover* magazine as one of the best science books of 2002; the American Library Association named it as one of the best histories of 2002.

2. Prior to writing *Mad in America*, I shared conventional beliefs about the nature of schizophrenia and the need for patients so diagnosed to be on antipsychotic medications for life. I had interviewed many psychiatric experts who told me that the drugs were like "insulin for diabetes" and corrected a chemical imbalance in the brain.

3. However, while writing a series for the *Boston Globe* during the summer of 1998, I came upon two studies that looked at long-term outcomes for schizophrenia patients that raised questions about this model of care. First, in 1994, Harvard researchers reported that outcomes for schizophrenia patients in the United States had declined in the past 20 years and were now no better than they had been in 1900.[1] Second, the World Health Organization twice found that schizophrenia patients in the poor countries of the world fare much better than in the U.S. and other "developed" countries, so much so that they concluded that living in a developed country was a "strong predictor" that a person so diagnosed would never recover.[2,3] Although the WHO didn't identify a reason for that disparity in outcomes, it did note a difference in the use of antipsychotic medications between the two groups. In the poor countries, only 16% of patients were regularly maintained on antipsychotic medications, whereas

[1] Hegarty, J, et al. "One hundred years of schizophrenia: a meta-analysis of the outcome literature." *American Journal of Psychiatry* 151 (1994):1409-16.
[2] Leff, J, et al. "The international pilot study of schizophrenia: five-year follow-up findings." *Psychological Medicine* 22 (1992):131-45.
[3] Jablensky, A, et al. "Schizophrenia: manifestations, incidence and course in different cultures, a World Health Organization ten-country study." *Psychological Medicine* 20, monograph supplement, (1992):1-95.

in the U.S. and other rich countries, this was the standard of care, with 61% of schizophrenia patients staying on the drugs continuously. (Exhibit 1)

4. I wrote *Mad in America*, in large part, to investigate why schizophrenia patients in the U.S. and other developed countries fare so poorly. A primary part of that task was researching the scientific literature on schizophrenia and antipsychotic drugs.

II. Overview of Research Literature on Schizophrenia and Standard Antipsychotic Medications

5. Although the public has often been told that people with schizophrenia suffer from too much "dopamine" in the brain, researchers who investigated this hypothesis during the 1970s and 1980s were unable to find evidence that people so diagnosed have, in fact, overactive dopamine systems. Within the psychiatric research community, this was widely acknowledged in the late 1980s and early 1990s. As Pierre Deniker, who was one of the founding fathers of psychopharmacology, confessed in 1990: "The dopaminergic theory of schizophrenia retains little credibility for psychiatrists."[4]

6. Since people with schizophrenia have no known "chemical imbalance" in the brain, antipsychotic drugs cannot be said to work by "balancing" brain chemistry. These drugs are not like "insulin for diabetes." They do not serve as a corrective to a known biological abnormality. Instead, Thorazine and other standard antipsychotics (also known as neuroleptics) work by powerfully blocking dopamine transmission in the brain. Specifically, these drugs block 70% to 90% of a particular group of dopamine receptors known as D2 receptors. This thwarting of normal dopamine transmission is what causes the drugs to be so problematic in terms of their side effects.

8. Psychiatry's belief in the necessity of using the drugs on a continual basis stems from two types of studies.

[4] Deniker, P. "The neuroleptics: a historical survey." *Acta Psychiatrica Scandinavica* 82, supplement 358 (1990):83-87.

a) First, research by the NIMH has shown that the drugs are more effective than placebo in curbing psychotic symptoms over the short term (six weeks).[5]

b) Second, researchers have found that if patients abruptly quit taking antipsychotic medications, they are at high risk of relapsing. [6]

9. Although the studies cited above provide a rationale for continual drug use, there is a long line of evidence in the research literature, one that is not generally known by the public or even by most psychiatrists, that shows that these drugs, over time, produce these results:

a) They increase the likelihood that a person will become chronically ill.
b) They cause a host of debilitating side effects.
c) They lead to early death.

III. Evidence Revealing Increased Chronicity of Psychotic Symptoms

10. In the early 1960s, the NIMH conducted a six-week study of 344 patients at nine hospitals that documented the efficacy of antipsychotics in knocking down psychosis over a short term. (See footnote five, above). The drug-treated patients fared better than the placebo patients over the short term. However, when the NIMH investigators followed up on the patients one year later, they found, much to their surprise, that it was the drug-treated patients who were more likely to have relapsed/ This was the first evidence of a paradox: Drugs that were effective in curbing psychosis over the short term were making patients more likely to become psychotic over the long term.[7]

---

[5] Cole, J, et al. "Phenothiazine treatment in acute schizophrenia." *Archives of General Psychiatry* 10 (1964):246-61.
[6] Gilbert, P, et al. "Neuroleptic withdrawal in schizophrenic patients." *Archives of General Psychiatry* 52 (1995):173-188.
[7] Schooler, N, et al. "One year after discharge: community adjustment of schizophrenic patients." *American Journal of Psychiatry* 123 (1967):986-95.

11. In the 1970s, the NIMH conducted three studies that compared antipsychotic treatment with "environmental" care that minimized use of the drugs. In each instance, patients treated without drugs did better over the long term than those treated in a conventional manner.[8, 9, 10] Those findings led NIMH scientist William Carpenter to conclude that "antipsychotic medication may make some schizophrenic patients more vulnerable to future relapse than would be the case in the natural course of the illness."

12. In the 1970s, two physicians at McGill University, Guy Chouinard and Barry Jones, offered a biological explanation for why this is so. The brain responds to neuroleptics and their blocking of dopamine receptors as though they are a pathological insult. To compensate, dopaminergic brain cells increase the density of their D2 receptors by 40% or more. The brain is now "supersensitive" to dopamine, and as a result, the person has become more *biologically* vulnerable to psychosis than he or she would be naturally. The two Canadian researchers wrote: "Neuroleptics can produce a dopamine supersensitivity that leads to both dyskinetic and psychotic symptoms. An implication is that the tendency toward psychotic relapse in a patient who had developed such a supersensitivity is determined by more than just the normal course of the illness. [11]

13. MRI-imaging studies have powerfully confirmed this hypothesis. During the 1990s, several research teams reported that antipsychotic drugs cause atrophy of the cerebral cortex and an enlargement of the basal ganglia.[12, 13, 14] In 1998, investigators at the

---

[8] Rappaport, M, et al. "Are there schizophrenics for whom drugs may be unnecessary or contraindicated?" *Int Pharmacopsychiatry* 13 (1978):100-11.

[9] Carpenter, W, et al. "The treatment of acute schizophrenia without drugs." *American Journal of Psychiatry* 134 (1977):14-20.

[10] Bola J, et al. "Treatment of acute psychosis without neuroleptics: two-year outcomes from the Soteria project." *Journal of Nervous Mental Disease* 191 (2003):219-29.

[11] Chouinard, G, et al. "Neuroleptic-induced supersensitivity psychosis." *American Journal of Psychiatry* 135 (1978):1409-10. Also see Chouinard, G, et al. "Neuroleptic-induced supersensitivity psychosis: clinical and pharmacologic characteristics." *American Journal of Psychiatry* 137(1980):16-20.

[12] Gur, R, et al. "A follow-up magnetic resonance imaging study of schizophrenia." *Archives of General Psychiatry* 55 (1998):142-152.

University of Pennsylvania reported that the drug-induced enlargement of the basal ganglia is "associated with greater severity of both negative and positive symptoms." In other words, they found that the drugs cause morphological changes in the brain that are associated with a worsening of the very symptoms the drugs are supposed to alleviate.[15]

IV. Research Showing that Recovery Rates are Higher for Non-Medicated Patients than for Medicated Patients.

14. The studies cited above show that the drugs increase the chronicity of psychotic symptoms over the long term. There are also now a number of studies documenting that long-term recovery rates are much higher for patients off antipsychotic medications. Specifically:

a) In 1994, Courtenay Harding at Boston University reported on the long-term outcomes of 82 chronic schizophrenics discharged from Vermont State Hospital in the late 1950s. She found that one-third of this cohort had recovered completely, and that all who did shared one characteristic: They had all stopped taking antipsychotic medication. The notion that schizophrenics needed to stay on antipsychotics all their lives was a "myth," Harding said.[16, 17, 18]

b) In the World Health Organization studies, 63% of patients in the poor countries had good outcomes, and only one-third became chronically ill. In the U.S.

---

[13] Chakos M, et al. "Increase in caudate nuclei volumes of first-episode schizophrenic patients taking antipsychotic drugs." *American Journal of Psychiatry* 151 (1994):1430-6.
[14] Madsen A, et al. "Neuroleptics in progressive structural brain abnormalities in psychiatric illness." *The Lancet* 352 (1998): 784-5.
[15] Gur, R, et al. "Subcortical MRI volumes in neuroleptic-naive and treated patients with schizophrenia." *American Journal of Psychiatry* 155 (1998):1711-17.
[16] Harding, C. "The Vermont longitudinal study of persons with severe mental illness," *American Journal of Psychiatry* 144 (1987):727-34.
[17] Harding, C. "Empirical correction of seven myths about schizophrenia with implications for treatment." *Acta Psychiatrica Scandinavica* 90, suppl. 384 (1994):140-6.
[18] McGuire, P. "New hope for people with schizophrenia," *APA Monitor* 31 (February 2000).

countries and other developed countries, only 37% of patients had good outcomes, and the remaining patients did not fare so well. In the undeveloped countries, only 16% of patients were regularly maintained on antipsychotics, versus 61% of patients in the developed countries.

c) In response to this body of literature, physicians in Switzerland, Sweden and Finland have developed programs that involve minimizing use of antipsychotic drugs, and they are reporting much better results than what we see in the United States.[19, 20, 21, 22] In particular, Jaako Seikkula recently reported that five years after initial diagnosis, 82% of his psychotic patients are symptom-free, 86% have returned to their jobs or to school, and only 14% of his patients are on antipsychotic medications.[23]

d) This spring, researchers at the University of Illinois Medical School reported on the long-term outcomes of schizophrenia patients in the Chicago area since 1990. They found that 40% of those who refused to take their antipsychotic medications were recovered at five-year and 15-year followup exams, versus five percent of the medicated patients.[24]

V. Harmful Side Effects from Antipsychotic Medications

[19] Ciompi, L, et al. "The pilot project Soteria Berne." *British Journal of Psychiatry* 161, supplement 18 (1992):145-53.
[20] Cullberg J. "Integrating psychosocial therapy and low dose medical treatment in a total material of first-episode psychotic patients compared to treatment as usual." *Medical Archives* 53 (199):167-70.
[21] Cullberg J. "One-year outcome in first episode psychosis patients in the Swedish Parachute Project. *Acta Psychiatrica Scandinavica* 106 (2002):276-85.
[22] Lehtinen V, et al. "Two-year outcome in first-episode psychosis according to an integrated model. *European Psychiatry* 15 (2000):312-320.
[23] Seikkula J, et al. Five-year experience of first-episode nonaffective psychosis in open-dialogue approach. *Psychotherapy Research* 16/2 (2006): 214-228.
[24] Harrow M, et al. "Factors involved in outcome and recovery in schizophrenia patients not on antipsychotic medications." *Journal of Nervous and Mental Disease* 195 (2007): 406-414.

15. In addition to making patients chronically ill, standard antipsychotics cause a wide range of debilitating side effects. Specifically:

a) Tardive dyskinesia. The most visible sign of tardive dyskinesia is a rhythmic movement of the tongue, which is the result of permanent damage to the basal ganglia, which controls motor movement. People suffering from tardive dyskinesia may have trouble walking, sitting still, eating, and speaking. In addition, people with tardive dyskinesia show accelerated cognitive decline. NIMH researcher George Crane said that tardive dyskinesia resembles "in every respect known neurological diseases, such as Huntington's disease, dystonia musculorum deformans, and postencephalitic brain damage."[25] Tardive dyskinesia appears in five percent of patients treated with standard neuroleptics in one year, with the percentage so afflicted increasing an additional five percent with each additional year of exposure.

b) Akathisia. This is an inner restlessness and anxiety that many patients describe as the worst sort of torment. This side effect has been linked to assaultive, murderous behavior.[26, 27, 28, 29, 30]

c) Emotional impairment. Many patients describe feeling like "zombies" on the drugs. In 1979, UCLA psychiatrist Theodore van Putten reported that most patients on antipsychotics were spending their lives in "virtual solitude, either staring vacantly at television, or wandering aimlessly around the neighborhood, sometimes stopping for a nap on a lawn or a park bench . . .

---

[25] Crane, G. "Clinical psychopharmacology in its 20th year," *Science* 181 (1973):124-128. Also see American Psychiatric Association, *Tardive Dyskinesia: A Task Force Report* (1992).
[26] Shear, K et al. "Suicide associated with akathisia and deport fluphenazine treatment," *Journal of Clinical Psychopharmacology* 3 (1982):235-6.
[27] Van Putten, T. "Behavioral toxicity of antipsychotic drugs." *Journal of Clinical Psychiatry* 48 (1987):13-19.
[28] Van Putten, T. "The many faces of akathisia," *Comprehensive Psychiatry* 16 91975):43-46.
[29] Herrera, J. "High-potency neuroleptics and violence in schizophrenia," *Journal of Nervous and Mental Disease* 176 (1988):558-561.
[30] Galynker, I. "Akathisia as violence." *Journal of Clinical Psychiatry* 58 (1997):16-24.

they are bland, passive, lack initiative, have blunted affect, make short, laconic replies to direct questions, and do not volunteer symptoms . . . there is a lack not only of interaction and initiative, but of any activity whatsoever.[31] The quality of life on conventional neuroleptics, researchers agreed, is "very poor." [32]

d) Cognitive impairment. Various studies have found that neuroleptics reduce one's capacity to learn and retain information. As Duke University scientist Richard Keefe said in 1999, these drugs may "actually prevent adequate learning effects and worsen motor skills, memory function, and executive abilities, such as problem solving and performance assessment."[33]

d) Other side effects of standard neuroleptics include an increased incidence of blindness, fatal blood clots, arrhythmia, heat stroke, swollen breasts, leaking breasts, obesity, sexual dysfunction, skin rashes and seizures, and early death.[34, 35, 36] Schizophrenia patients now commit suicide at 20 times the rate they did prior to the use of neuroleptics.[37]

VI. The Research Literature on Atypical Antipsychotics

---

[31] Van Putten, T. "The board and care home." *Hospital and Community Psychiatry* 30 (1979):461-464.
[32] Weiden P. "Atypical antipsychotic drugs and long-term outcome in schizophrenia." *Journal of Clinical Psychiatry* 57, supplement 11 (1996):53-60.
[33] Keefe, R. "Do novel antipsychotics improve cognition?" *Psychiatric Annals* 29 (1999):623-629.
[34] Arana, G. "An overview of side effects caused by typical antipsychotics." *Journal of Clinical Psychiatry* 61, supplement 8 (2000):5-13.
[35] Waddington, J. "Mortality in schizophrenia." *British Journal of Psychiatry* 173 (1998):325-329.
[36] Joukamaa, M, et al. Schizophrenia, neuroleptic medication and mortality. *British Journal of Psychiatry* 188 (2006):122-127.
[37] Healy, D et al. "Lifetime suicide rates in treated schizophrenia." *British Journal of Psychiatry* 188 (2006):223-228.

16. The conventional wisdom today is that the "atypical" antipsychotics that have been brought to market—Risperdal, Zyprexa, and Seroquel, to name three—are much better and safer than Haldol, Thorazine and the other older drugs. However, it is now clear that the new drugs have no such advantage, and there is even evidence suggesting that they are worse than the old ones.

17. Risperdal, which is manufactured by Janssen, was approved in 1994. Although it was hailed in the press as a "breakthrough "medication, the FDA, in its review of the clinical trial data, concluded that there was no evidence that this drug was better or safer than Haldol (haloperidol.) The FDA told Janssen: "We would consider any advertisement or promotion labeling for RISPERDAL false, misleading, or lacking fair balance under section 501 (a) and 502 (n) of the ACT if there is presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness."[38]

18. After Risperdal (risperidone) was approved, physicians who weren't funded by Janssen were able were able to conduct independent studies of the drug. They concluded that risperidone, in comparison to Haldol, caused a higher incidence of Parkinsonian symptoms; that it was more likely to stir akathisia; and that many patients had to quit taking the drug because it didn't knock down their psychotic symptoms.[39, 40, 41, 42, 43] Jeffrey Mattes, director of the Psychopharmacology Research Association, concluded in 1997: "It is possible, based on the available studies, that risperidone is not as effective as

---

[38] FDA approval letter from Robert Temple to Janssen Research Foundation, December 21, 1993.
[39] Rosebush, P. "Neurologic side effects in neuroleptic-naïve patients treated with haloperidol or risperidone." *Neurology* 52 (1999):782-785.
[40] Knable, M. "Extrapyramidal side effects with risperidone and haloperidol at comparable D2 receptor levels." *Psychiatry Research: Neuroimaging Section* 75 (1997):91-101.
[41] Sweeney, J. "Adverse effects of risperidone on eye movement activity." *Neuropsychopharmacology* 16 (1997):217-228.
[42] Carter, C. "Risperidone use in a teaching hospital during its first year after market approval." *Psychopharmacology Bulletin* 31 (1995):719-725.
[43] Binder, R. "A naturalistic study of clinical use of risperidone." *Psychiatric Services* 49 (1998):524-6.

standard neuroleptics for typical positive symptoms."[44] Letters also poured into medical journals linking risperidone to neuroleptic malignant syndrome, tardive dyskinesia, tardive dystonia, liver toxicity, mania, and an unusual disorder of the mouth called "rabbit syndrome."

19. Zyprexa, which is manufactured by Eli Lilly, was approved by the FDA in 1996. This drug, the public was told, worked in a more "comprehensive" manner than either risperidone or haloperidol, and was much "safer and more effective" than the standard neuroleptics. However, the FDA, in its review of the trial data for Zyprexa, noted that Eli Lilly had designed its studies in ways that were "biased against haloperidol." In fact, 20 of the 2500 patients treated with Zyprexa in the trials died. Twenty-two percent of the Zyprexa patients suffered a "serious" adverse event, compared to 18 percent of the Haldol patients. There was also evidence that Zyprexa caused some sort of metabolic dysfunction, as patients gained nearly a pound per week. Other problems that showed up in Zyprexa patients included Parkinsonian symptoms, akathisia, dystonia, hypotension, constipation, tachycardia, seizures, liver abnormalities, white blood cell disorders, and diabetic complications. Moreover, two-thirds of the Zyprexa patients were unable to complete the trials either because the drugs didn't work or because of intolerable side effects.[45]

20. There is now increasing recognition in scientific circles that the atypical antipsychotics are no better than the old drugs, and may in fact be worse. Specifically:

a) In 2000, a team of English researchers led by John Geddes at the University of Oxford reviewed results from 52 studies, involving 12,649 patients. They concluded: "There is no clear evidence that atypicals are more effective or are better tolerated than conventional antipsychotics." The English researchers noted that Janssen, Eli Lilly and other manufacturers of atypicals had used

[44] Mattes, J. "Risperidone: How good is the evidence for efficacy?" *Schizophrenia Bulletin* 23 (1997):155-161.
[45] See Whitaker, R. *Mad in America*. New York: Perseus Press (2002):279-281.

various ruses in their clinical trials to make their new drugs look better than the old ones. In particular, the drug companies had used "excessive doses of the comparator drug."[46]

b) In 2005, a National Institute of Mental Health study found that that were "no significant differences" between the old drugs and the atypicals in terms of their efficacy or how well patients tolerated them. Seventy-five percent of the 1432 patients in the study were unable to stay on antipsychotics owing to the drugs' "inefficacy or intolerable side effects," or for other reasons.[47]

c) In 2007, a study by the British government found that schizophrenia patients had better "quality of life" on the old drugs than on the new ones.[48] This finding was quite startling given that researchers had previously determined that patients medicated with the old drugs had a "very poor" quality of life.

20. There is also growing evidence that the atypicals may be exacerbating the problem of early death. Although the atypicals may not clamp down on dopamine transmission quite as powerfully as the old standard neuroleptics, they also block a number of other neurotransmitter systems, most notably serotonin and glutamate. As a result, they may cause a broader range of physical ailments, with diabetes and metabolic dysfunction particularly common for patients treated with Zyprexa. In a 2003 study of Irish patients, 25 of 72 patients (35%) died over a period of 7.5 years, leading the researchers to conclude that the risk of death for schizophrenics had "doubled" since the introduction of the atypical antipsychotics. [49]

---

[46] Geddes, J. "Atypical antipsychotics in the treatment of schizophrenia." *British Medical Journal* 321 (2000):1371-76.
[47] Lieberman, J, et al. "Effectiveness of antipsychotic drugs in patients with schizophrenia." *New England Journal of Medicine* 353 (2005):1209-1233.
[48] Davies, L, et al. "Cost-effectiveness of first- v. second-generation antipsychotic drugs." *The British Journal of Psychiatry* 191 (2007):14-22.
[49] Morgan, M, et al. "Prospective analysis of premature morbidity in schizophrenia in relation to health service engagement." *Psychiatry Research* 117 (2003):127-35.

VII. Conclusion

21. In summary, the research literature reveals the following:

a) Antipsychotics increase the likelihood that a person will become chronically ill.

b) Long-term recovery rates are much higher for unmedicated patients than for those who are maintained on antipsychotic drugs.

c) Antipsychotics cause a host of debilitating physical, emotional and cognitive side effects, and lead to early death.

d) The new "atypical" antipsychotics are not better than the old ones in terms of their safety and tolerability, and quality of life may even be worse on the new drugs than on the old ones.

DATED this ___ day of September, 2007, in Cambridge, Massachusetts.

_____
Robert Whitaker

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 2007.

_____
Notary Public in and for Massachusetts
My Commission Expires:_____

AFFIDAVIT OF RONALD BASSMAN, PhD

STATE OF NEW YORK)
) ss.
ALBANY COUNTY)

Is Medication for Serious Mental Illnesses the Only Choice For All People?
By Ronald Bassman, PhD

Albert Einstein once said that the definition of insanity is doing the same thing over and over again and expecting different results.

Today, the primary treatment for people who are diagnosed with serious mental illness is psychiatric medications regardless of effectiveness.[1] Institutions are filled with those who have failed to progress despite numerous trials on medications over the course of many years.[2] Current treatments for serious mental illnesses ignore research evidence showing debilitating conditions arising from the use of psychiatric medications.[3] Adults with serious mental illness treated in public systems die about 25 years earlier than Americans overall, a gap that's widened since the early 1990s when major mental disorders cut life spans by 10 to 15 years.[4] Along with shorter life spans, people taking psychiatric medication typically have medication-caused disabilities that make it extremely difficult for them to find employment and to become fully integrated members of the community. Not only do they show impairment in cognitive and motor abilities but also must live with physical distortions of appearance that make them extremely reluctant to be seen in public places.

Founded in 1988, the Tardive Dyskinesia/Tardive Dystonia National Association has received thousand of letters and inquiries from individuals taking psychiatric medications and who struggle with the adverse effects. Tardive dyskinesia, dystonia and akathisia are late appearing neurological movement disorders caused by psychoactive drugs.[5] The following letters were received by the Tardive Dyskinesia/Tardive Dystonia National Association:[6]

"Tremors and spasms make my arms do a sort of jitterbug. Spasms in my neck pull my head to the side. My tongue sticks out as often as every thirty seconds."

- T.D. Survivor, Washington, DC

"Having TD is being unable to control my arms, fingers and sometimes my facial muscles; having a spastic digestive tract and trouble breathing. Getting food from my plate to my mouth and chewing it once there can be a real chore. I've bitten my tongue so severely it's scarred. I often bite it hard enough to bleed into the food I'm trying to eat. I no longer drink liquids without drooling."

- T.D. Survivor, New York

"I've always tried to feel better and I felt how could any prescribed medicine meant to help me, do more damage than the illness itself."

- T.D. Survivor, Louisiana

I am a person who was first diagnosed with schizophrenia paranoid type and then after another hospitalization diagnosed with schizophrenia chronic type and who was prescribed numerous psychiatric drugs including Thorazine Stelazine and Mellaril. I have been drug-free for more than thirty years. Having had personal experience with psychiatric medication and recovered after withdrawing from the prescribed drugs, I have subsequently worked as a psychologist to develop and promote alternative healing practices.[7] I have written and published articles in professional journals and in 2005 co-founded the International Network of Treatment Alternatives for Recovery.[8]

Research, my own and others, in addition to the numerous personal accounts of recovery without psychiatric medications, coupled with the documented adverse effects demand that we respect a person's choice -- choices which are based on personal experience and preference for other methods of coping and progressing toward recovery and re-integration into the community.[9] Psychiatric medication is and should be only one of many treatment choices for the individual with serious mental illness. And when it is clear that medications are not effective, it is necessary and only humane to offer other options for the individual to choose. Primary to the recovery process is personal choice.

The National Research Project for the Development of Recovery Facilitating System Performance Indicators concluded that, "Recovery from mental illness can best be understood through the lived experience of persons with psychiatric disabilities." The Research Project listed the following themes as instrumental to recovery:

*Recovery is the reawakening of hope after despair.
*Recovery is breaking through denial and achieving understanding and acceptance.
*Recovery is moving from withdrawal to engagement and active participation in life.
*Recovery is active coping rather than passive adjustment.
*Recovery means no longer viewing oneself primarily as a mental patient and reclaiming a positive sense of self.
*Recovery is a journey from alienation to purpose.
*Recovery is a complex journey.
*Recovery is not accomplished alone—it involves support and partnership.[10]

Research describing what people want and need is very similar to what everyone wants and needs. The best practices of psychosocial rehabilitation highlight the following:

1. Recovery can occur without professional intervention. The consumer/survivors rather than professionals are the keys to recovery.

2. Essential is the presence of people who believe in and stand by the person in need of recovery. Of critical importance is a person or persons whom one can trust to be there in times of need.

3. Recovery is not a function of one's theory about the causes of mental illness. And recovery can occur whether one views the condition as biological or not.

4. People who experience intense psychiatric symptoms episodically are able to recover. Growth and setbacks during recovery make it feel like it is not a linear process. Recovery often changes the frequency and duration of symptoms for the better. The process does not feel systematic and planned.

5. Recovery from the consequences of the original condition may be the most difficult part of recovery. The disadvantages, including stigma, loss of rights, discrimination and disempowering treatment services can combine to hinder a person's recovery even if he or she is asymptomatic.[11]

In the above concepts promoting recovery there is a conspicuous absence of psychiatric medication. Psychologist Courtenay Harding, principal researcher of the "Vermont Longitudinal Study," has empirically demonstrated that people do recover from long-term chronic disorders such as schizophrenia at a minimum rate of 32 % and as high as 60%.[12] These studies have consistently found that half to two thirds of patients significantly improved or recovered, including some cohorts of very chronic cases. The 32 % for full recovery is with one of the five criteria being *no longer taking any psychiatric medication.* Dr. Harding in delineating the seven myths of schizophrenia, addresses the myth about psychiatric medication. Myth number 5. **Myth: Patients must be on medication all their lives. Reality: It may be a small percentage who need medication indefinitely.** According to Harding and Zahniser, the myths limit the scope and effectiveness of treatments available to patients.[13]

The most important principle of the medical profession is one that has stood the test of time. "First do no harm." When it is clear that psychiatric medications have been ineffective and/or harmful in the treatment of a particular individual, and when that person objects to another treatment course with psychiatric drugs, it is wrong to continue on this course against the expressed wishes of that individual. One must consider the statement attributed to Albert Einstein at the beginning of this affidavit. Let us work with people to implement their informed choices for alternative services and not continue trying to implement a treatment that has not worked.

DATED this _____ day of September, 2007, in Albany, New York.

_____
Ronald Bassman, PhD

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 2007.

_____
Notary Public in and for New York
My Commission Expires:_____

REFERENCES

[1] Stip E. Happy birthday neuroleptics! 50 years later: la folie du doute. Eur Psychiatry,17(3):115-119, 2002.

[2] The President's New Freedom Commission for Mental Health. Transforming Mental Health Care: Achieving the Promise, Rockville, MD, 2005.

[3]Jeffrey A. Lieberman, M.D., T. Scott Stroup, M.D., M.P.H., Joseph P. McEvoy, M.D., Marvin S. Swartz, M.D., Robert A. Rosenheck, M.D., Diana O. Perkins, M.D., M.P.H., Richard S.E. Keefe, Ph.D., Sonia M. Davis, Dr.P.H., Clarence E. Davis, Ph.D., Barry D. Lebowitz, Ph.D., Joanne Severe, M.S., John K. Hsiao, M.D., for the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Investigators Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia, Vol.353:1209-1223, No.12, 2005.

[4] Parks, J. Morbidity and mortality in people with serious mental illness. Fifth National Summit of State Psychiatric Hospital Superintendents, May 6-8, 2007.

[5] Breggin, P. Brain damage, dementia and persistent cognitive dysfunction associated with neuroleptic drugs: Evidence, etiology, implications. Challenging the Therapeutic State: Critical Perspectives on Psychiatry and the Mental health System, ed. David Cohen, Journal of Mind Behavior 11.3-4 p. 425-464. 1990.

[6]Bassman, R. Mental illness and the freedom to refuse treatment: privilege or right. Professional Psychology: Research and Practice, Vol.36, No.5, 488-497, 2005.

[7] Bassman, R. The mental health system: Experiences from both sides of the locked doors. Professional Psychology: Research and Practice, Vol. 28, No. 3, 238-242 1997.

[8] Bassman, R. A Fight to Be: A Psychologist's Experience from Both Sides of the Locked Door. Tantamount Press: Albany, New York, 2007.

[9] Bassman, R. Consumer/Survivors/Ex-patients as change facilitators, in Frese, F. ed. The Role of Organized Psychology in Treatment of the Seriously Mentally Ill, New Directions for Mental Health, No. 88, Winter, p. 93-102, 2000.

[10] Onken S. et al. Mental Health Recovery: What Helps and What Hinders: A National Research Project for the development of Recovery Facilitating System Performance Indicators, Prepared for National Technical Assistance Center for State Mental Health Planning, National Association of State Mental Health Program Directors, 2002.

[11]Anthony W. Recovery from mental illness: The guiding vision of the mental health system in the 1990s, An Introduction to Psychiatric Rehabilitation, ed. The Publications Committee of IAPRS, Boston University, 1994.

[12] Harding C.M., Brooks G.W., Ashikaga T., Strauss J.S. and Breier A. The Vermont longitudinal study of persons with severe mental illness, I: Methodology, study sample, and overall status 32 years later. Am J Psychiatry; 144:718-726, 1987.

[13] Harding C.M. Zahniser J.H. Empirical correction of seven myths about schizophrenia with implications for treatment. Acta Psychiatr Scand, 90 (suppl 384): 140-146, 1994.

Sarah Porter Testimony in Alaska Case

A. I've worked in the mental health [field] in New Zealand for the last 15 years in a variety of roles. I'm currently employed as a strategic advisor by the Capital and Coast District Health Board. I'm currently doing a course of study called the Advanced Leadership and Management in Mental Health Program in New Zealand. And, in fact, the reason I'm here is, I won a scholarship through that program to study innovative programs that are going on in other parts of the world so that I could bring some of that information back to New Zealand. I also have personal experience of using mental health services which dates back to 1976 when I was a relatively young child. . . . set up and run a program in New Zealand which operates as an alternative to acute mental health services. It's called the KEYWA Program. That's spelled K-E-Y-W-A. Because it was developed and designed to operate as an alternative to the hospital program that currently is provided in New Zealand. That's been operating since December last year, so it's a relatively new program, but our outcomes to date have been outstanding, and the funding body that provided with the resources to do the program is extremely excited about the results that we've been able to achieve, with people receiving the service and helping us to assist and [starting] out more similar programs in New Zealand.

Q You're a member of the organization called INTAR, is that correct?

A I am a member of INTAR, which is the International Network of Treatment Alternatives for Recovery. And I'm also a member of the New Zealand Mental Health Foundation, which is an organization in New Zealand that's charged with the responsibility for promotion of mental health and prevention of mental disability in New Zealand.

Q Okay. Are there -- can you describe a little bit what INTAR is about?

A INTAR is an international network of people who are interested in promoting the knowledge about, and availability of access to alternatives to traditional and mainstream approaches to treating mental distress. And INTAR is really interested in identifying successful methods of working with people experiencing distress to promote mental well being, and, in particular, alternatives to the use of mainstream medical model or medication type treatments.

Q And are there people in INTAR that are actually running those kind of programs?

A There are. There's a wide variety of people doing that. And some of them are, also, themselves, interestingly, have backgrounds in psychiatry and psychology.

Q . . . Are there members of INTAR who are psychiatrists?

A There are. Indeed. Yes, indeed.

Q Do you know -- do you remember any of their names?

A Dr. Peter Stastny is a psychiatrist, Dr. Pat [Bracken], who manages the mental health services in West Cork, Ireland, and also in parts of England, as a psychiatrist. . .

Q Okay. Is it fair to say that all these people believe that there should be other methods of treating people who are diagnosed with mental illness than insisting on medication?

A Absolutely, there are. And that's quite a strong theme, in fact, for -- for that group, and I believe that it's based on the fact that there is now growing recognition that medication is not a satisfactory answer for a significant proportion of the people who experience mental distress, and that for some people...it creates more problems than solutions. . . .

Q. Now, I believe you testified that you have experience dealing with those sorts of people as well, is that correct?

A I do.

Q And would that include someone who has been in the system for a long time, who is on and off drugs, and who might refuse them?

A Yes. Absolutely. We've worked with people in our services across the spectrum. People who have had long term experience of using services and others for whom it's their first presentation.

Q And when you say "long term use of services," does that include -- does that mean they need medication?

A Unfortunately, in New Zealand the primary form of treatment, until very recent times, has been medication, through the lack of alternatives. . . . And we're just now beginning to develop alternatives. They'd offer people real choice and options in terms of what is available instead of medication that might enable people to further address the issues which are raised by the concerns related to their mental state.

Q And I think I understood you to say that the program that you run along that line has had very good outcomes, is that correct?

A It has. The outcomes to date have been outstanding. The feedback from services users and from other people working with the services -- both, peoples families and the clinical personnel working with those people has supported the approach that we have taken.

Q And is -- and I think you said that, in fact, it's been so impressive that the government is looking at expanding that program with more funding?

A Indeed. And, in fact, right across New Zealand they are now looking at what can be done to create -- make resources available to set up…more such services in New Zealand. . .

Q Is there a philosophy that you might describe in terms of how -- that would go along with this kind of alternative approach?

A The way that I would describe that is that it's -- it's really about relationships. It's about building a good therapeutic relationship with the person in distress and supporting that person to recognize and come to terms with the issues that are going on in their life, in such a way that builds a therapeutic alliance and is based on negotiation, rather than the use of force or coercion, primarily...

A ...because we recognize that the use of force and coercion actually undermines the therapeutic relationship and decreases the likelihood of compliance in the long term with whatever kinds of treatment or support has been implicated for the person. So we have created and set up our service along the lines of making relationship and negotiation the primary basis for working with the person and supporting the person to reflect on and reconsider what's going on to create what might be defined as a crisis, and to devise strategies and

plans for how the person might be with the issues and challenges that they face in their life. . . .

Q Now, you mentioned -- I think you said that coercion creates problems. Could you describe those kind of problems?

A Well, that's really about the fact that [there is] growing recognition -- I think worldwide, but particularly in New Zealand, that coercion, itself, creates trauma and further distress for the person, and that that, in itself, actually undermines the benefits of the treatment that is being provided in a forced context. And so our aiming and teaching is to be able to support the person to resolve the issues without actually having to trample...on the person's autonomy, or hound them physically or emotionally in doing so.

Q And I think you testified that would be --include people who have been in the system for a long time, right?

A It does, indeed. Yes.

Q And would that include people who have been coerced for a long time?

A In many cases, yes. . . .

Q And -- and have you seen success in that approach?

A We have. It's been phenomenal, actually. Jim, I've been -- personally, I -- I had high hopes that it would work, but I've...been really impressed how well, in fact, it has worked.

Documents to be Produced

1. All trials, studies, or reports initiated, supported or sponsored by Janssen relating to Risperdal, including any conducted outside the United States. This includes those trials, studies, and reports for any New Drug Application (NDA) or Investigational New Drug (IND) application, including any supplemental applications.

2. For those studies published or presented at any major medical meeting(s), a copy of all publications and abstracts and all other materials given to participants.

3. All documents relating to Risperdal provided to FDA advisory committees;

4. The following documents relating to Risperdal from FDA approval to the present time:

a. All presentation, training sessions, or materials given to employees or agents who marketed or otherwise promoted Risperdal, including speakers and consultants;

b. All pamphlets, literature, and other information to be shown or given to physicians by sales representatives, and also provide all related communications;

c. Any other communications provided to healthcare providers regarding the safety and efficacy of Risperdal, and all related communications;

d. All internal or external presentation or reports based on the marketing plan for Risperdal, and all communications related to the presentations or reports;

e. All internal or external presentations or reports related to physicians prescribing patterns including data on specialty or prescriber and indications for use, and all communications related to these presentations or reports;

f. All internal or external presentations or reports relating to continuing medical education, and all communications related to these presentations or reports;

g. All internal or external presentations or reports relating off-label use, and all communications related to these presentations or reports;

h. All documents relating to funding support provided for nonprofit professional medical organizations or consumer/patient organizations; and

i. All marketing department correspondence with nonprofit professional medical organizations or consumer/patient organizations.

Manner of Production

I. This subpoena applies to electronic records as well as physical documents. Format issues shall be handled as provided in the Federal Rules of Civil Procedure.

II. This subpoena applies to all documents in your possession, custody, or control, or any combination thereof.

III. Documents responsive to this subpoena should not be destroyed, modified, removed, transferred, or otherwise made inaccessible.

IV. Each document produced should be produced in a form that renders the document capable of being copied.

V. Documents produced should identify the paragraph or clause that responds to the subpoena.

VI. Documents produced should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this subpoena was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.

VII. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the subpoena to which the documents are responsive, should be provided in an accompanying index.

VIII. If any of the subpoenaed information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with James B. Gottstein to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure call for in VI & VII above. Documents produced in an electronic format should also be produced in a searchable format.

IX. If any document responsive to this subpoena was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipient(s)) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

X. If a date or other descriptive detail set forth in this subpoena referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the description in this subpoena, you must produce all documents which would be responsive as if the date or other descriptive detail were correct.

XI. This subpoena is continuing in nature, until further notice, or the underlying matter has been terminated, whichever is earlier, and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

XII. All documents should be bates-stamped sequentially and produced sequentially.

Representative(s) Who Can Respond to the Following:

With respect to Item No. 1, above, to the extent such information is not contained within the documents brought to the trial, an authorized representative(s) of Janssen who can answer the following questions with respect to the materials required to be produced above. Written response(s) under oath, in lieu of attendance by a Janssen representative will suffice.

- **A.** The name of the author(s) and physician(s) that participated;
- **B.** The number of participants;
- **C.** The date it was initiated, completed, or terminated, if terminated, explaining the reason(s) behind the termination;
- **D.** Summarization of the methodology, findings, and conclusions;
- **E.** The extent to which the marketing department provided funding or other support;
- **F.** The extent to which compensation or benefit(s), monetary or otherwise (including support or assistance in creating manuscripts), was provided to any author, physician, or participant;
- **G.** If not published or presented, an explanation for why the study was not published or presented.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contacts, cables, notations of any type of conversation, telephone call, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, massages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alternations, modifications, revisions, changes, and amendments of any of the foregoing, as well as nay attachments or appendices thereto). The term also means any graphic or oral records or representations or any kind (including without limitation, photographs, charts, graphs,

voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representation of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recording), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is separate document within the meaning of this term.

2. The term "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure or exchange or information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, person delivery, or otherwise.

4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to by outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains embodies, reflects, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.