A Patient Bill of Rights for Psychotropic Prescriptions

A Call for a Higher Standard of Care

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A Critical Perspective
A Patient Bill of Rights

Of all tyrannies, a tyranny sincerely exercised for the good of its victims may be the most oppressive.
C.S. Lewis

A Patient Bill of Rights
The Story of Ann

Cautious, careful people, always casting about to preserve their reputation and social standing, never can bring about a reform. Those who are really in earnest must be willing to be anything or nothing in the world's estimation, and publicly and privately, in season and out, avow their sympathy with despised and persecuted ideas and their advocates, and bear the consequences.

Susan B. Anthony

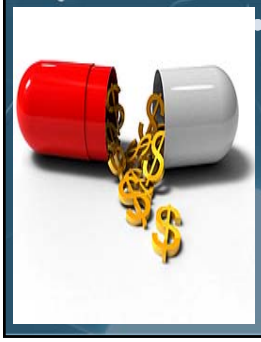
Unprecedented Marketing And the Transition to Primary Care Venues

- Spending for psychotropics increased from nearly $8 billion in 1997 to $20 billion in 2004, reaching over $40 billion in sales in 2011
- Concurrently, the use of psychotherapy has declined and community behavioral intervention has fallen or remained flat.

Justified by the Clinical Trial Evidence? Hard to Get an Accurate Picture

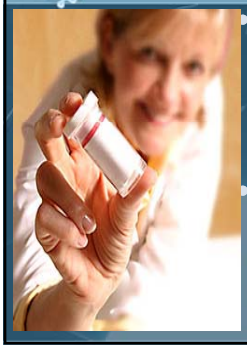
Marcia Angell: "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly & reluctantly over my two decades as an editor of *NEJM*."

Pharmaceutical Company Influence It's Everywhere, It's Everywhere



- Extends to Internet, print, & broadcast media, direct-to consumer-advertising, "grassroots" consumer-advocacy, prof. guilds, medical schools, docs, & research—even the FDA. So, press reports, web pages, & even academic literature can be unreliable.

Compounding the Problem The Transition to Primary Care



- Primary care docs often do not have the time, formal education, & training to properly evaluate the clinical trial literature, or to know the range of treatment options available.
- The unfortunate result is an over reliance on psychotropics as a first line intervention and an under-reliance on safer and comparably effective psychosocial options.

This Presentation Duncan & Antonuccio, 2011

- Calls for a higher standard of prescriptive care derived from a risk/benefit analysis of clinical trial evidence. Many current prescribing practices are empirically unsound and unduly influenced by pharmaceutical company interests, which tend to inflate benefits/minimize risk.

In the Spirit of EBM & Health Home A Patient Bill of Rights

- The Bill of Rights is the 1st 10 amendments to the Constitution. It limits the power of the US Gov. protecting the rights of liberty, freedom of speech, free press, free assembly, & freedom from cruel & unusual punishment.
- Here, a bill of rights preserves the autonomy & freedom of patients prescribed psychotropic drugs in the hopes of creating an evolving document & ongoing discussion.

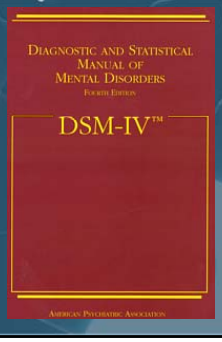
Patient Bill of Rights: 1

- **Patients have a right to a thorough diagnostic and functional assessment by a behavioral health care specialist.**

Diagnosis in Behavioral Healthcare

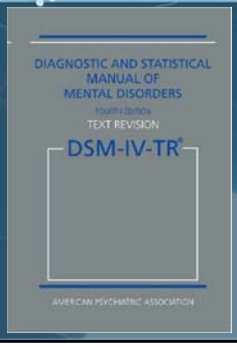
While critical to evidence-based medical tx, dx in beh. healthcare has notoriously poor reliability & validity. Over-reliance on symptom-based dx view can lead to a "pill for every ill." More important than a dx label is an assessment of how a patient's problems impact his or her life & what can be done about it.

The Killer D's of Client Diminishment



- ✓Dysfunction
- ✓Disorder
- ✓Disability
- ✓Disease
- ✓Deficit
- ✓Damaged
- ✓Not Reliable or Valid
- ✓None ever related to outcome

Diagnosis



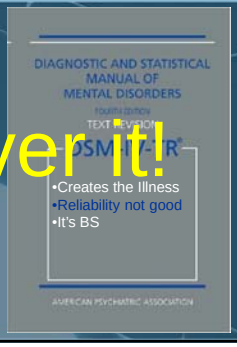
"I have found little that is good about human beings. In my experience, most of them are trash."
--Sigmund Freud, M.D.

More Quotable Quotes about Diagnosis

"Psychotherapy is the only form of treatment which, at least to some extent, appears to create the illness it treats" **Jerome Frank** (Frank, 1961, p. 7).

Reliability: "To say that we've solved the reliability problem is just not true…It's been improved. But if you're in a situation with a general clinician it's not very good. There's still a real problem, and it's not clear how to solve the problem" **Robert Spitzer**, lead editor of DSM III (Spiegel, 2005, p. 63).

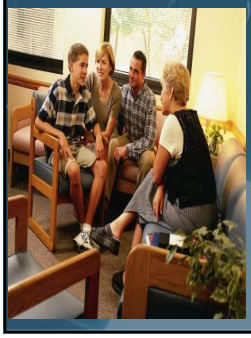
Validity: "There is no definition of a mental disorder. It's bullshit. I mean, you just can't define it… these concepts are virtually impossible to define precisely with bright lines at the boundaries." **Allen Francis**, lead editor of DSM IV (Greenberg, 2010, p. 1).



Get Over it!

- •Creates the Illness
- •Reliability not good
- •It's BS

Closely Aligned with a Heath Home and Integrated Care Perspective

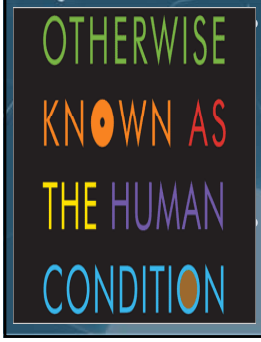


- •Assessment gathers info from all involved & includes dev., env., familial, & sociocultural aspects
- •Since 50% of patients referred for MH services do not FU, it is best that the assessment & tx be a part of routine care.
- •Recent meta-analysis reported improvements in both mental & physical health when brief therapy was incorporated in primary care settings.

Change Is Afoot

A substantial protest to the upcoming DSM V has mounted. The Society for Humanistic Psychology in alliance with several other APA Div. as well as professional organizations from around the world has circulated a petition entitled "An Open Letter to the DSM-5" Visit: http://www.ipetitions.com/petition/dsm5/?utm_medium=email&utm_source=system&utm_campaign=Send%2Bto%2BFriend

1. Patients have a right to a thorough diagnostic and functional assessment by a behavioral health care specialist.



- Includes possibility that the problem(s) may be described as part of the human condition or a natural response to stress. poverty, injustice; Or the right *not* to have normal behavior labeled as pathological.
- Pharmaceutical marketing has led to "disease mongering," or the creation or expansion of disorders to increase revenues .

Disease Mongering?

- Study: # of visits of youth w/bipolar disorder, 1994-1995 v. 2002-2003. A 40-fold increase; questionable despite explanations of advances in detection.
- 90+% treated w/drugs; despite evidence, most prescribed > 1; 4/10 received therapy.
- Thorough assess. starts with an understanding of person w/i the realm of normal human beh.

Patient Bill of Rights: 2

- **Patients have a right to be informed about the safety & efficacy of treatment options including psychological treatment alone, medication alone, combined treatments, as well as no treatment.**

Informed Consent
Data-Based Risk/Benefit Analysis

The risks & benefits of any intervention should be transparently discussed. Open discussions allow patients to decide which tx offers the best option in line with their own values and cultural contexts

Risk/Benefit Analysis: TADS
(*Treatment of Adolescent Depression Study*)

- Multicenter, randomized, masked, effectiveness trial funded by NIMH. N=432
- Short term (12-weeks) & long-term (36-weeks) of adols. diagnosed w/MDD
- 4 groups: Prozac, placebo, CBT, Prozac + CBT
- Primary measures: CDRS and dichotomized CGI-I

Risk/Benefit Analysis: TADS
(*Treatment of Adolescent Depression Study*)

- ✓CBT alone had comparable outcome at 30 weeks while the antidepressant treatment groups had significantly more psychiatric adverse events;
- ✓Six suicide attempts occurred in the medication groups v. one in the nonmedication group

Suicide Related Events (SREs, includes SAs) and Suicide Attempts (SAs) in the TADS (see, Vitiello et al., 2009)

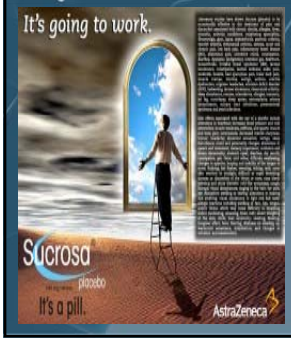
Treatment	N	SREs	%	SAs
Placebo	103	3	3	0
CBT	108	5	5	1
Fluoxetine alone	109	16	15	6
Combination	107	9	8	3
Placebo switched to fluoxetine or combination	9	9	100	6
CBT switched to fluoxetine or combination	3	2	67	2
Total Non-SSRI	211	8	4	1
Total SSRI	228	44	19	18

Risk/Benefit Analysis
(Recent Meta-analytic Studies)

✓Similarly, patients should be informed about recent meta-analytic data showing that antidepressants are not more effective than placebo except for a small portion of patients in the very severe range.

✓Kirsch et al., 2008; Fournier et al., 2010

Placebo Should Be...



- The treatment of choice for depression

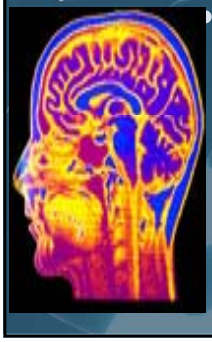
Risk/Benefit Analysis
(Recent Meta-analytic Studies)

•Despite minimal benefits, SSRIs were most prescribed drug in 2011

•Patients should also be informed about the likely outcome of no tx at all.

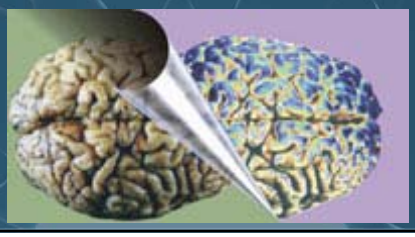
•Problems often improve w/o intervention. Remission ranges from 20% to 60% fo episode of depression .

Risk/Benefit Analysis
Biological Markers & Chemical Imbalances



- Should also be informed that science has yet to reliably identify any biological markers or chemical imbalances for any psychiatric dx; no evidence that any drug repairs imbalances or proposed neurochemical substrates.

Despite fifty years of Herculean efforts, the invention of electron microscopy, the advent of radiolabeling techniques, the revolution of molecular biology, and the merger of computers with neuroimaging machines, no reliable biological marker has ever emerged as the definitive cause of any psychiatric "disease."



Risk/Benefit Analysis
Biological Markers & Chemical Imbalances

Understanding the limits of scientific understanding paves the way for an informed choice about treatment options.

Patient Bill of Rights: 3

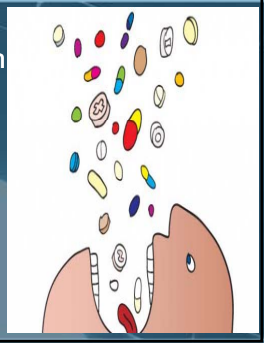
- **Patients have a right to be treated with psychosocial interventions alone if they so choose.**

Based on the Evidence Regarding the Efficacy and Safety

- of psychiatric meds, a risk/benefit analysis suggests that therapy be considered first, depending on preferences. Patients, therefore, have a right to be treated by a physician who sees psychosocial options as viable first line, stand alone treatments

Psychotherapy Outperforms Medication in the Long Run

- Alternatives should be discussed: Stress reduction techniques, support groups, psychotherapy, exercise & nutrition, problem solving, familial, spiritual, peer & community support for emotional and behavioral problems



In the Case of Depression Psychological Treatments

- Are as effective as medication in the short run with more durable benefits in the long run, even if the depression is severe
- Although combined treatments are touted as the best option, they are not better than psychotherapy alone over the long term but they have better results than medication alone

Patient Bill of Rights: 4

- **Patients have a right to be exposed to the lowest risk of adverse events from psychotropic medications—a right to a "first do no harm approach."**

In Psychotropic Medications
First Do No Harm

- Not aware of any scientific studies addressing the combination of more than two psychotropic medications, so this should be the upper limit. Even two medication combinations have been rarely studied, and when they have, underwhelming results seem the norm

STAR*D
Sequenced Tx Alternatives to Relieve Depression

- STAR*D: examined impact of augmentation or med switching strategies for depression when a traditional regimen of a single SSRI failed.
- Ave. remission rate on primary outcome measure was 28% (Level 1) and 25% (Level 2—augmented or switched), or a total of 39%.
- Each level as a different episode, an average remission rate of 27%; Moderate to intolerable adverse events were experienced by 28% of participants at Level 1 & 51% at Level 2.

Two SSRIs
First Do No Harm

Combining Medications to Enhance Depression Outcomes (CO-MED) study showed that a single antidepressant produced the same remission rate as combined antidepressants and that therapy with 2 medications resulted in more adverse events.

Off Label and Polypharmacy
First Do No Harm

- Prescribing w/o FDA approval, off-label prescribing should also be rare; Altho polypharmacy & off label prescriptions tend to expose patients to increased risks & side effects, such practices are popular, particularly in vulnerable populations of children and the elderly.

Study of poor children found that 26% on antipsychotics; Poor children 4 times more likely to be on antipsychotics

57% of foster children are taking 3 or more psychiatric drugs, 6 times national average

Apparently, children are vulnerable to psychotropics used as interventions of control rather than therapy.

Short Term Intervention
First Do No Harm

Patients have a right for psychotropic medications to be used as *primarily* a short term treatment. Most of the scientific database consists of controlled studies of 6 to 12 weeks in duration. There are not enough controlled investigations beyond 12 weeks to guide patients or prescribers in terms of safety & efficacy. When longer trials are done, results are unimpressive.

Long Term Results
First Do No Harm

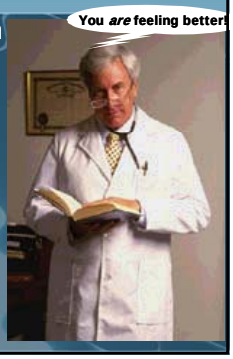
- STAR*D: 58% of those who responded through the four levels relapsed at one year follow-up.
- CATIE, a study of antipsychotics w/adults w/schizophrenia: 74% discontinued before 18 months, due to inefficacy & side effects.
- TEOSS, a study of antipsychotics w/youth w/schizophrenia: 12% of youth both responded and stayed on antipsychotics for a year.
- Long term use of psychotropics does not appear to be empirically supported.

Patient Bill of Rights: 5

- **Patients have a right to monitor their treatment response with patient rated outcome measures.**

Patient Rated Measures
Patient versus Clinician Ratings

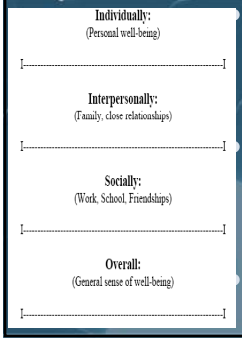
- Patients & clinicians differ on impressions of improvement
- Outcome measures are most often clinician-rated
- When patient ratings are used, no difference results
- If patients don't notice advantage over placebo, how significant are ratings by others?



Patient Rated Measures

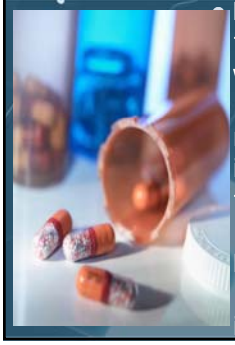
- A meta-analysis of 22 antidepressant studies (*N* = 2230) found that antidepressants showed an approximate 20% advantage over placebo on clinician-rated measures, but *none* on patient-rated
- This is the rule rather than the exception

Patient Rated Measures



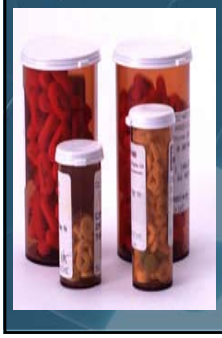
- Using patient-rated measures allows more accurate assess. of benefit & may improve outcomes.
- Using client-rated measures improves outcomes in therapy, allows tailoring of interv. based on response.
- Allows patients to change approach if not working.

Patient Rated Measures
In the Absence of Benefit



- Patients also have a right *not* to have their dosage incr. A weak dose/response relationship w/psychotropic meds. Response does not improve w/doses higher than those already in the rec. range, e.g., w/SSRIs. However, side effects & the risk of adverse events increase with higher doses.

Patient Rated Measures In the Absence of Benefit



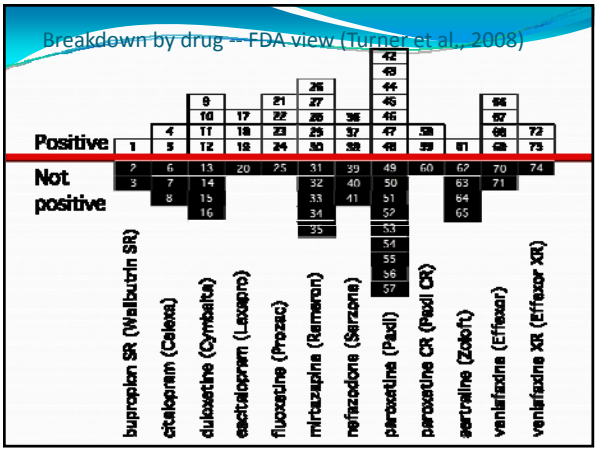
Patients have a right to be tapered off ineffective meds before additional ones are prescribed given that augmentation studies have shown limited benefits. In other words, patients have a right to experience a med free period to see if they feel better before a new one is added.

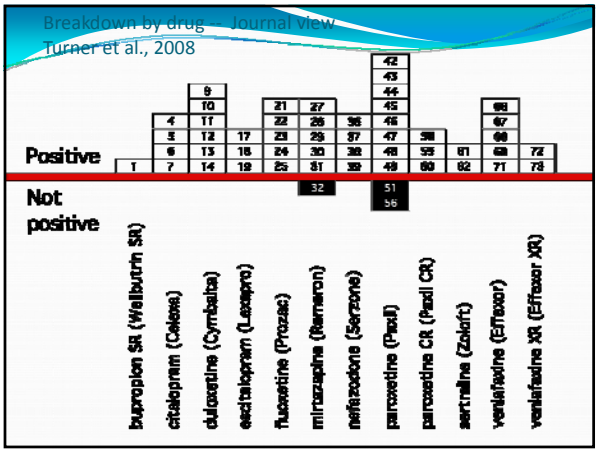
Patient Bill of Rights: 6

- **Patients have a right to untainted scientific data conveyed in a consumer friendly way regarding psychotropic medication.**

Untainted Data Base

- A public database of all published & unpublished data; the risks/benefits free of spin and marketing.
- Scientific database is distorted by ghost written articles & skewed by publication bias, i.e., publishing studies that are favorable to the pharmaceutical industry products, sometimes recasting unfavorable outcomes into the conclusion that the medication is "efficacious, safe, and well tolerated."
- Until an unvarnished database that includes all the data becomes available, the Cochrane database may serve as the best resource.

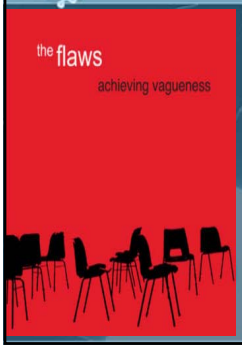




Translating The Patient BORs To A Higher Standard of Care

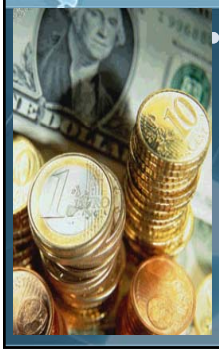
- Informed consent after full disclosure of the risks and benefits of psychotropic prescription.
- Psychosocial options first consistent w/preference.
- Practices that are not empirically-supported should be limited (and include full consent & close monitoring).
- Patient rated measures of outcome should be used in both research and practice.
- Pharmaceutical company influence should be separated from science and practice.
- A data base of the risks and benefits of psychotropics, independent of industry influence, should be available.

Conclusions
Flawed Methodology



Needs reform: analysis to detect penetration of double blind and/or the use of psychoactive placebos; pt. rated measures; long term eval. of efficacy and safety; inclusion of investigators w/o pharm. co. affiliations; & independent reporting of findings to remove spin.

Regarding Practice
Untainted Information



- Pharm. Co. press releases and "detailing" from sales reps should include indep. eval. of claims & non-med. options. Incentives and benefits should be eliminated. Psychosocial interv. have neither marketing reps nor budgets—a more concerted effort to include them is needed.

The STAR*D
Determining Science from Spin

- STAR*D: Posited a 67% cumulative remission rate but qualified: "...assumes no dropouts, and it assumes that those who exited the study would have had the same remission as those who stayed in the protocol."
- As the 67% figure is often repeated while the unrealistic assumptions on which it is based are forgotten, it is easy for prescribers to conclude that augmentation/switch strategies are soundly supported.

The STAR*D
Determining Science from Spin

- If one looks at the remission across all levels, which at each level was quite meager and less than typical placebo response, combined with a 51% adverse reaction profile after augmentation/switch, and a 58% relapse rate, a different conclusion would likely result.
- After a year of treatment following remission, of the 4,041 patients who entered the program only 108 (3%) had a sustained remission—all others either dropped out or relapsed.

Conclusions

- The unprecedented promotion of the pharm. industry forms basis of meds centrality.
- While some may be helped, it directs primary care away from safer interv. w/comparable efficacy—therapy, as well as other community-based options.
- And, it promotes txs of ? sustainability, dangerous effects

A Patient Bill of Rights
Evidenced Based Medicine

- Proposed a patient BORs & guidelines that embody a higher standard of care, making the patient a partner in the decisions about tx.
- Such a collaboration allows the integration of the best research evidence w/clinical expertise and patient values.
- The proposed guidelines align the prescriber w/the patient, the evidence, and the outcome of intervention, and perhaps more importantly, the commitment to first do no harm.