THE STATE OF SOUTH CAROLINA

IN THE COURT OF APPEALS

Appeal from York, County

Lee S.Alford, Circuit Court Judge

THE STATE,

RESPONDENT,

v.

BEN ROBERT STEWART,

APPELLANT,

Pro se; APPELLANT BRIEF

BEN ROBERT STEWART
BEN STEWART#HK9369
1 Kelley Drive
Coal Township,Pa. 17866-1021

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2. Whether the trial Court spoke as an expert as to the Appellant's ability to conduct a defense while on psychiatric medication, constituted as a violation of the Appellant's due process ?

3. Whether a expert is needed to determine a matter out-side of common knowledge of a lay person ?

4. Whether a conviction of the Appellant while he was incompetent at trial violates due process ?

STATEMENT OF THE CASE

The Appellant Ben Robert Stewart, Ben Stewart #HK9369 was jointly tried with co-defendant Terrell Addison before a jury during the February, 2009 term of the York County General Sessions Court before the Honorable, Lee S.Alford, Judge.

The Appellant was found guilty of accessory before the fact to murder, accessory before the fact to robbery, accessory before the fact to kidnapping, accessory after the fact to armed robbery, kidnapping, and murder, criminal conspiracy and possession of a firearm during the commission of a violent crime .

The Appellant was sentenced to an imprisonment for an aggregated period of thirty years (30) which is to run after completion of his current term in Pennsylvania of between 8 and 16 years which ever comes first.

Although trial counsel filed timely motion to appeal no counsel was appointed to the Appellant until July of 2010 when the Appellant filed an application for post conviction relief(PCR) February of 2010 before the Appellant became bared, claiming that the Appellant was not provided with an Appellate attorney and the Appellant could not pay for trial transcript. Once the Appellant was appointed counsel for this appeal,counsel filed an Anders Brief indicating that this appeal is without appealable grounds and requested to be relieved as the Appellant's counsel pursuant to;Anders v. California, 386 U.S. 738,87 S.Ct. 1396 18 L.E.2d. 493 (1967).

Also which is stated in Anders v. California, by Justice, STEWART, J,BLACK, and J,HARLAN, said in regards to this procedure, "But if the record did present any such arguable issues, the appeal would not be frivolous and counsel would not have filed a no merit letter in the first place, Therefore, the pro se; Appellant files this brief...

FACTS OF THE CASE

Prior to the jury being sworn, the State presented mental evaluation reports to determine both Appellant and co-defendant competency to stand trial. Based off the mental evaluations it indicated that the defendants were both competent .

Upon this motion, Trial Court questioned both defenses as to their positions regarding the evaluations reports .

There was no objections as to co-defendant's competency, but through trial counsel the Appellant indicated that (He) Appellant, was under psychiatric medication. Counsel for the Appellant told the Trial Court that the Appellant was was taking prozac. The Trial Court asked the Appellant whether it was the Appellant's position that (He) Appellant was incompetent to stand trial. Counsel for the Appellant asked the Trial Court to consider that matter being that the Appellant was under medication and did not know and or could not rule on such an matter.

Trial Court based it's decision on the Appellant's mental evaluation rather then the evidence of the Appellant being on medication at trial.

Trial Court gave opinion as to the Appellant's ability to conduct a defense at trial under psychiatric medication.
R.p 35, lines 11-20

ARGUMENT

1. The trial Court denied the Appellant a hearing as to competency to stand trial with insufficient determination as to the mental competency of the Appellant, which violated the Appellant's Due Process.

When the trial Court continued the trial, that led to the Appellant being denied a hearing as to competency to stand trial and not affording the Appellant due process with insufficient determination as to competency of the Appellant. This case followed; Dusky v. United States, 362 U.S.402 (1960). Dusky v. United States, addresses the precise issue raised in this case, Judgment was reversed,on grounds of the insufficient of the record to support the District Court's finding that the accused was mentally competent to stand trial, futhermore, The United States Supreme Court determines that the record does not sufficiently support the accused was mentally competent to stand trial and there are doubts and ambiguities regarding the legal significance of the psychiatric testimony in the case giving rise to difficulties of determining retrospectively the accused's competency as of time of trial, the Judgment of the Court of Appeals will be reversed and the case will be remanded to the District Court for a new trial if he is found competent.

As in this case, the trial Court based it's decision on an evaluation and not on the Appellant that went to trial. The Appellant was denied due process by trial Court's failure to conduct a hearing upon the Appellant's competency to stand trial, and there is no doubt that the record does not support the lower Court's finding of the Appellant being mentally competent to stand trial. Another case that rests with this matter is; Pate v. Robinson,383 U.S 375 (1966).

Pate v. Robinson addresses that the respondent Robinson, was convicted in an unduly hurried trial without a fair opportunity to obtain expert psychiatric testimony and without sufficient development of the fact on the issue of his competency to stand trial. The Court of Appeals remanded the case to the District Court with directions to hold a hearing as to whether the respondent had been denied due process by the state's Court failure to conduct a hearing upon his competency to stand trial.(345f.2d.691).

On certiorari, the United States Supreme Court affirmed except as to the Court of Appeals direction that the District Court hold a hearing involving the respondent's competency. In an opinion by; Clark J,. expressing the views of seven members of the Court, it was held that the respondent was constitutionally entitled to a hearing on the issue of his competency to stand trial, but since it was too late for the District Court to conduct a meaningful hearing on that issue, the case would be remanded to the District Court with directions that it order the respondent discharge after affording the state an opportunity to try him again within a reasonable time.

2. Trial Court spoke as an expert as to Appellant's ability to conduct a defense while on psychiatric medication, which constituted as a violation of due process.

At trial, the trial Court stated the following; R.p 35, lines 11-20 .

> COURT; All right, sir. You know, I'm basing my decision, he's been evaluated and they found him competent to stand trial. Plenty of people take Prozac and other antidepressants and they are still able to understand and ready to proceed and assist counsel with defense and render him competent. If he feels he has a problem with his understanding and being able to assist his attorney with the defense of the case, then he should say so. All right, but he choose not say so. At any rate, I find based on all the information in front of me, including the mental evaluations, mental health evaluations, he's competent to stand trial and able to assist counsel

with his defense and is ready to proceed with trial.

(END OF R.)

Hear, trial Court ruled that Appellant was competent to stand trial and explained how various people could function under medication, which was clearly error. The decision the trial Court made was not merely the issue at hand prior to trial. The Appellant was concern about the medication that Appellant told the trial Court about it because it more then likely have side effects. Nevertheless, it was not Appellant nor the trial Courts duty to decide the likely or unlikely side effects of psychiatric medication.

> Washington v. Harper, answers this. Washington v. Harper,494 U.S. 210 (1990) Supreme Court J, Kennedy, held that (3) Administrative procedures set by policy, including provision for review by administrative panel as opposed to judicial decision makers, comported with requirements of procedural due process. Haper,Id. at. 231. states; notwithstanding the risk that are involved, we conclude that an inmate's interest are adequately protected, and perhaps better served, by medical professionals rather then a judge.

A mere inquiry on the Appellant's competency at trial was abandon, the trial Court was suppose to look further on about the Appellant's competency before trial. Drope v. Missouri, apply's to this. In,

> Drope v. Missouri, 420 U.S. 162 (1974) The United States Supreme Court reversed and remanded, In an opinion by Burger, Ch.J. expressing the unanimous views of the Court, it held (1) the defendant's due process right to a fair trial was violated by the trial Court's failure to suspend the trial pending a psychiatric examination to determine the defendant's competency to stand trial. Furthermore, this Court goes back to there decision in Pate v. Robinson, Id. at [420 U.S. 180] [10] and that explains; " that evidence of a defendant's irrational behavior, his demeanor at trial, and any prior medical opinion on competency to stand trial are all relevant in determining whether further inquiry is required, but that even one of these factors

standing alone may, in circumstances, be sufficient. Drope, Id:at, [420 U.S. 818] [1d] [11] [12a] states;"Even when a defendant is competent at the commencement of his trial, a trial Court must always be alert to circumstances suggesting a change that would render the accused unable to meet the standard of competence to stand trial. Whatever the relationship between mental illness and competent to stand trial, in this case the bearing of the former on the latter was sufficiently likely that, in light of the evidence of petitioner's behavior including his suicide attempt, and there being no opportunity without his presence to evaluate that bearing in fact, the correct course was to suspend the trial until such an evaluation could be made".

In this case, it meets the standard of Drope, although the Appellant didn't attempt to commit suicide, there was clearly circumstances that suggested a change of mental competency of the Appellant, and the trial Court did not evaluate such evidence by affording the Appellant an hearing as to competence to stand trial while on psychiatric medication, but in fact gave an opinion as a expert to such circumstances.

3. Expert testimony is essential where the topic is not a matter within common knowledge of a lay person.

Considering the facts in this case, under Rule 701, SCRE as to sub. (c) the Court of Appeals has stated; " that expert testimony is essential where the topic is not a matter within the common knowledge and experiences of most lay person. See; Suartanburg Regional Med. Center v. Bulsa, 308 S.C. 322 417 S.E. 2d. 648 (Ct. App. 1992). Also, Rule 702, SCRE, scientific, technical, or other specialized knowledge will assist the tire of fact to understanding the evidence or to determine a fact in issue. Hear, it was not done in this case. Under Rule 3, CJC, 501. (7) (a) SCACR,where circumstances require, expert communication for scheduling, administrative purpose or emergences that do not deal with substantive matters or issues on the merits are authorized; To the contrary,

however, under Rule 3, CJC, 501. (7) (e) A judge may initial or consider any expert communication when expressly authorized by law. But, Commentary to sec. (e) states; " An appropriate and often desirable procedure for a Court to obtain the advice of a disinterested expert on legal issues is to invite the expert to file a brief amicus. Hear, the trial Court choose not to which, gave the Appellant an unfair trial. This falls under the case of; United States v. Damon, 191 F.3d 561 (1999). This case explains;

> Defendant's guilty pleas remanded for determination of whether any drugs taken by the defendant had the capacity to impair his judgment sufficiently to render him incapable to entering a knowing and voluntary plea. In opinion by; Judge Williams, that wrote a dissenting opinion, Id at; (191 F.3d 567) 1. stated; "Although Dusky v. United States, 362 U.S. 402, 4 L.Ed. 2d. 842, 80 S.Ct. 788 (1960), dealt with a defendant's competency to stand trial, the standard for competence to enter a plea of guilty is the same as that for competence to stand trial. See; Godinez v. Moran, 509 U.S. 389, 125 L.Ed. 2d. 321, S.Ct. 2680 (1993). Also, Judge, Williams, Id. at; (191 F.3d. 567) 2. stated; As this Court recently noted, " it is essential to an orderly working of the criminal justice system that guilty pleas tendered and accepted in conformity with Rule 11... be presumed final". United States v. Sparks, 67 F.3d. 1145, 1154 (4th. Cir. 1995) Accordingly, Damon's guilty plea should be treated as final.

According to this case at hand, there was no guilty plea. The Appellant was not afforded a fair trial when the trial Court did not conduct a hearing as to the Appellant's competence to stand trial, the trial Court gave it's opinion of various people including the Appellant's ability to conduct a defense, and the record has a insufficient finding as to the Appellant's competency and there was no expert to conclude that there was no side effects of the psychiatric medication, which all denied the Appellant the benefit of a fair trial. These errors violated Rule 3,CJC, (7) (a), Rule 3, CJC, (e) Commentary Rule 701, SCRE, and Rule 702, SCRE.

4. A conviction of the Appellant while he was incompetent at trial violates due process.

Prior to the jury being sworn, the Appellant told the trial Court that(He) Appellant was under psychiatric medication through trial counsel. The following was stated at trial; R.p 34, line. 21-p. 35, line.10.

> MR. SNOW: Your Honor, I just ask that the record reflect my client has just asked me to indicate to the judge that he is on medication.
> THE COURT: What is he taking?
> MR. SNOW: He's taking Prozac, judge.
> THE COURT: Okay. And is it his position that he's not competent to stand trial or that would help you or assist you with your defense of his case?
> MR. SNOW: Judge, he's --he's submitting that before the judge to consider -- he's leaving it to the judge to decide whether he's competent.
> THE COURT: I don't know what games he's playing in that regards, Mr. Snow, and if wishes to be heard, I will be glad to hear from him.
> MR. SNOW: Nothing further, judge.

(END OF R.)

At that point, the trial Court denied the Appellant a right to a fair trial while the Appellant was under psychiatric medication, suffering from the following side effects of Fluoxetine antidepressant that is prescribed for treatment of depression. **EXHIBIT.A** refer's to what Fluoxetine is, the brand name is; PROZAC.

EXHIBIT B. explains since the age (8) eight the Appellant has been receiving mental health treatment. In 2006, prior to being incarcerated, Appellant was diagnosed with Cyclothymia disorder, Cyclothymia is a disorder milder form of Bipolar II disorder, conissting of recrrent mood disturbances between hypomania and dysthymic mood.

When the Appellant was incarcerated in 2007 there was no medical attention until the Appellant was sentenced to prison in Pennsylvania. In prison, the Appellant was treated with the same medication (Prozac) when Appellant came to the State of South Carolina. During the three year spand since the Appellant

was last diagnosed with Cyclothymia, there was no long observation as to determining if the Appellant developed into full bipolar disorder. **EXHIBIT-C. p.** 3. (under lined) explains that Cyclothymia eventually develop into bipolar disorder.

Although there has been an evaluation on the Appellant the trial Court did not explain the contents of the evaluation.

EXHIBIT-D. explains the brain of a person having bipolar.

Going back to the record of the trial, trial Court gave an opinion as to how people could conduct a defense and be able to understand the trial while on antidepressants. **EXHIBIT-E.** explains what (Prozac) is. page.(1)(under lined) and page (3) explains"it may impair your thinking or reactions".

EXHIBIT-F. explains the side effects, Common side effects are; Page.(1) (under lined) anxiety, drowsiness, nervousness. The severe side effects at page. (3)(under lined) are; Bizarre behavior, confusion, decreased coordination, hallucination, aggressiveness, exaggerated feelings of well being, suicidal thoughts or attempts.

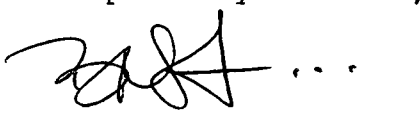
At trial, the Appellant did not experience all of the above mention, however the Appellant did have side effects of anxiety, nervousness, confusion. Again, as for side effects and general provision of the antidepressant(Prozac) see; **EXHIBIT-G. p.** (2) and page (3).

As in the present time the Appellant is not ... taking Prozac antidepressant but taking another antidepressant for treatment. Accordingly,for the mentioned in this appeal of the insufficient record to support the lower Court's finding of the Appellant being competent to stand trial, the Appellant being denied a hearing as to competency because the Appellant was taking psychiatric medication, the trial Court ruled that the Appellant was competent to stand trial while on medication, and no expert/ psychiatric examiner,determined that the Appellant was competent to stand trial, which violated the Appellant's due process..

CONCLUSION

Based on the argument presented, the Appellant ask's this Honorable Court to reverse and remand this case to the lower Court's for a new trial after having a hearing as to the Appellant's competency to stand trial, and or any reason this Court finds just.

Respectfully Submitted,



Ben Robert Stewart-

Ben Stewart-HK9369

Lay men Pro se;Appellant

Brief,.-

This day of August, 21 ,2012

THE STATE OF SOUTH CAROLINA
IN THE COURT OF APPEALS

Appeal from York, County
Lee S.Alford, Circuit Court Judge

THE STATE, RESPONDENT,

v.

BEN ROBERT STEWART APPELLANT,

PROOF OF SERVICE

I, the Appellant, Ben Robert Stewart, certify that I have served an Appellant pro se; brief to The South Carolina Court of Appeals and also served (3) copies with the Clerk. At; Post Office Box 11629, Columbia SC. 29911.

This day of August 21 2012

Ben Robert Stewart-HK9369
1 Kelley Drive
Coal Township PA 17866-1021

Exhibit A

Fluoxetine

Fluoxetine, type of drug known as an antidepressant, prescribed for the treatment of depression, particularly depression lasting longer than two weeks and interfering with daily functioning. Fluoxetine works by regulating serotonin levels in the brain. Serotonin is a neurotransmitter, a chemical in the body's nervous system associated with maintaining a general sense of well-being. An insufficient amount of serotonin in the brain may contribute to depression. Fluoxetine may also be prescribed for treatment of other conditions related to insufficient levels of serotonin including eating disorders (obesity and bulimia), obsessive-compulsive disorder, and premenstrual syndrome.

Fluoxetine, available by prescription only, is taken orally in tablet form. The effectiveness of fluoxetine is not altered by food, so the medication can be taken on an empty or full stomach. When fluoxetine is prescribed to treat depression, the usual dose ranges from 20 to 60 mg per day. It usually requires three to four weeks for the patient to feel the effects. After the medication begins to take effect, the dose may be lowered. A lower dose may be sufficient for treatment of conditions other than depression.

Fluoxetine should not be taken in combination with other types of antidepressants known as monoamine oxidase (MAO) inhibitors. Taking these medications at the same time or even within a month of one another has serious, sometimes fatal results. At least five weeks must be allowed between the last dose of fluoxetine and the first dose of a MAO inhibitor. Fluoxetine is not recommended for people recovering from heart attack, or for those with kidney or liver disease, diabetes, or a history of seizures. Women who are pregnant or breast-feeding are advised not to take fluoxetine, and people taking it should not consume alcohol.

Common adverse side effects of fluoxetine include anxiety, insomnia, headaches, dizziness, changes in appetite, weight loss, nausea, and diarrhea.

Brand Name: *Prozac*

Exhibit B

LIST OF EXHIBITS

Claimant: **Ben Robert Stewart, III** **SSN:** **191-66-4959**

Wage Earner: **Ben R Stewart** **Xref SSN:** **248-70-5464**

Exh. No.	Part No.	Description	No. of Pages
		MEDICAL RECORDS	
1	F	Development Summary Worksheets	4
	F	Letter from The Children's Hospital of Philadelphia dated December 1, 2005, stating patient last seen in 1994, no records since that date	1
3	F	Consultative (Clinical Psychological) Examination with Medical Source Statement dated January 19, 2006 by Charles Johnson, PSY.D., with professional qualifications	7
4	F	RFC - Residual Functional Capacity Assessment - Mental dated January 24, 2006	3
5	F	Psychiatric Review Technique Form dated January 24, 2006	13

WILKES-BARRE
BRANCH

01/19/2006
DATE DICTATED

PENNSYLVANIA BUREAU OF DISABILITY DETERMINATION
264 Highland Park Blvd., Wilkes-Barre, PA 18703
TRANSCRIPTION OF TELERECORDED MESSAGE

ADJUDICATOR: J. SAITA

CHARLES JOHNSON, PSY.D.
267 S. 44TH ST.
PHILA, PA 19104

RE: STEWART, BEN

SSN: 191-66-4959

PHONE: 215-222-0755

DATE: 01/20/2006

REPORT NUMBER: 698688

TDN#: 0111308062

CLINICAL PSYCHOLOGICAL DISABILITY EVALUATION

BEHAVIOR OBSERVATION:

Ben Stewart is a 19-year-old, African-American male who was punctual for his appointment. He arrived by a car with his mother. He was the sole source of the information derived from this evaluation. His reporting reliability would be judged as adequate. Authorization document indicates a disability claim of dyslexia and bipolar disorder.

PRESENTING COMPLAINTS:

Ben stated that, "It's hard to remember, anger - I have a quick temper, I find myself being bored all the time, and I can't sleep." His mother added that Ben tends to walk "all the time, has plenty of energy."

Ben indicated that he has been experiencing the above for the past five years since around the age of 10. As a result of this condition, he claims, "I forget things - things that I'm told to do." Note: He indicates that he at times does feel hyper, tending to pace ~~and pacing~~ around the room.

SUBSTANCE USE HISTORY:

Ben indicated he began drinking alcohol at the age of 18 with "occasional use," e.g. on holidays. He last had four-five shots on New Year's Eve. He did experiment with marijuana at the age of 16, but claimed that he has not used any marijuana since that age.

EXHIBIT NO: 3F
PAGE 1 OF 7

PSYCHOSOCIAL HISTORY:

Ben was born and reared in Philadelphia. His biological father died in 2003 from emphysema. He has 10 half brothers and sisters. He is currently in the twelfth grade, attending Bartram High School, special education program. He did work part time for Pathmark during the summer in 2004; however, he quit after working one month, stating he did not like the job. He feels that he can work sometimes, other times he feels "it's too hard." He is currently living with his mother and stepfather.

MEDICAL/PSYCHIATRIC HISTORY:

Ben indicated that he sustained an injury to his left ear as a result of being bitten by a dog at the age of 4. In addition, he was hit by a car and sustained injury to his teeth, again at the age of 4.

Ben has received psychiatric treatment at CHOP (Children's Hospital of Philadelphia) around the age of 10 for behavioral problems and for "forgetfulness." He received a psychiatric treatment at the JFK Mental Health Clinic, beginning in August 2005. He was receiving help with his anger.

MEDICATIONS:

Ben was prescribed Ritalin but was discontinued, and switched apparently to albuterol with notable therapeutic benefit; however, he discontinued the medication and attending JFK in December 2005.

MEDICAL ISSUES:

Ben disclaimed having any medical conditions or concerns at this time.

MENTAL STATUS EXAMINATION:

Ben is an average-built male of casual dress, who appeared his stated age. Psychomotor movements were unremarkable. Speech was clear and comprehensible with eye contact. Mood and affect was subdued. Note: He denied feeling depressed but acknowledged feeling bored. He complained of difficulty sleeping with a tendency to average five-six hours a night. He eats once or twice a day, although it is mainly "junk food." Auditory and visual hallucinations were denied. Thought processes were logical and coherent. Thought content was devoid

of suicidal ideation and delusional themes. Paranoia was acclaimed, e.g., "I feel that people are looking at me." Abstraction of relevant concepts was fair, e.g., he was able to associate the similarity between an orange and a banana, a dog and a lion, and a table and a chair. Attention span and concentration were marginal. He was able to recall four digits forward and three digits backwards. Arithmetic computation was fair, e.g., he was able to subtract $7.50 from $18 correctly.

Ben was oriented to time, place and person. Memory for recent, recent past and remote events was intact, e.g., he was able to recall yesterday's dinner in addition to the event of his last birthday in November. Tested social judgment was fair, e.g., he indicated that he would give a stamped, sealed envelope lying on a sidewalk to a mailman and that he would tell someone who worked in a theater in the event that a fire occurred. Impulse control was marginal. Insight was fair.

TYPICAL DAILY FUNCTIONING:

Ben indicated that he spends his day listening to music and doing school homework. He occasionally visits a friend but usually just sits around the house. Note: He does attend school on a daily basis. He does participate in routine housekeeping task, e.g., taking out the trash, washing the dishes and sweeping the floors, although his mother stated that she needs to remind him of these tasks. He is attentive to normal hazards and precautions in routine travel. He can and does utilize public transportation unaccompanied. He feels he can make his own decisions without assistance.

MULTIAXIAL DIAGNOSES:

AXIS I: Cyclothymic Disorder.
Bipolar Disorder, NOS (provisional).
AXIS II: No diagnosis.
AXIS III: No medical condition known.

PROGNOSIS:

Ben presents a guarded prognosis with respects to pursuing psychiatric treatment in the future.

CAPABILITY:

Ben would be expected to require some assistance in a reasonable management of his own funds.

CHARLES JOHNSON, PSY.D.

CYMED/698688

"THIS TRANSCRIPTION WAS MADE FROM THE RECORDING OF THE VOICE OF CHARLES JOHNSON, PSY.D.-A COPY OF THIS REPORT HAS BEEN SENT TO THE DOCTOR FOR REVIEW AND SIGNATURE."

Dear Doctor:

Thank you for promptly telerecording the preceding medical report. The transcription has been included as evidence in this applicant's disability claim.

Enclosed you will find two (2) copies of transcription. Please review the material and make any necessary revisions on the copies. An amended copy will be sent to you if there are substantial revisions.

Please sign and return one copy WITHIN THREE DAYS; payment of this report will be delayed until we receive your signed copy. The other copy is for your files.

(1) Is ability to understand, remember, and carry out instructions affected by the impairment? ____ No ✓ Yes
If "no", go to question #2. If "yes", please check the appropriate block to describe the individual's restriction for the following work-related mental activities.

	None	Slight	Moderate	Marked	Extreme
Understand and remember short, simple instructions.	✓				
Carry out short, simple instructions.	✓				
Understand and remember detailed instructions.		✓			
Carry out detailed instructions.		✓			
Make judgments on simple work-related decisions.			✓		

What medical/clinical finding(s) support this assessment?

Clinical Interview
Mental Status Exam (Number Recall; Similarities, Soc Judgmt, Arith)

(2) Is the ability to respond appropriately to supervision, co-workers, and work pressures in a work setting affected by the impairment? ____ No ✓ Yes
If "no", go to question #3. If "yes", please check the appropriate block to describe the individual's restriction for the following work-related mental activities.

	None	Slight	Moderate	Marked	Extreme
Interact appropriately with the public.	✓				
Interact appropriately with supervisor(s).			✓		
Interact appropriately with co-workers.		✓			
Respond appropriately to work pressures in a usual work setting.			✓		
Respond appropriately to changes in a routine work setting.			✓		

What medical/clinical finding(s) support this assessment?

Clinical Interview

01113080 62

1/24/06 jfan

5-

(3) Are any other capabilities affected by the impairment? ✓ No ____ Yes
If "yes", please identify the capability and describe how it is affected.

Capability	Effect

What medical/clinical findings support this assessment?

(4) If the claimant's impairment(s) include alcohol and/or substance abuse, do these impairments contribute to any of the claimant's limitations as set forth above? If so, please list the specific limitations caused.

(5) If you have concluded that the medical record indicates that the claimant's alcohol and/or substance use/abuse contributes to any limitations as set forth above, please identify and explain what changes you would make to your answers if the claimant was totally abstinent from alcohol and/or substance use/abuse.

(6) Can the individual manage benefits in his/her own best interest?
✓ No ____ Yes

Charles S Johnson, Psy.D — Physician's/Psychologist's Signature
Psychologist — Medical Specialty
1/19/06 — Date

01113080 62

051899
164 5/03

6

PROFESSIONAL QUALIFICATIONS

1. **Name:** Charles S. Johnson, PSYD
   First/Middle/Last

   Address: 4401 Spruce Street

   Philadelphia, PA 19104

Cannot be found in: (circle # of book searched)

1. American Medical Association 36th Edition – CD Rom
2. Directory of American Psychological Association 1997 Edition
3. American Osteopathic Yearbook and Directory 200/01

Exhibit C

Cyclothymia

Sci-Tech Dictionary:

cyclothymic disorder

(ˌsī·klə'thī·mik dis'örd·ər)

(*psychology*) A mild form of bipolar disorder in which the intensity of the depressive or manic episodes does not reach full criteria.

Medical Dictionary: cy·clo·thy·mic disorder

(sī'klə-thī'mĭk)
n.

A chronic mood disturbance generally lasting at least two years and characterized by mood swings including periods of hypomania and depression.

Wikipedia: Cyclothymia

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Please help improve this article by adding citations to reliable sources. Unverifiable material may be challenged and removed. *(July 2007)*

Cyclothymia

Classification and external resources

ICD-10	F34.0
ICD-9	301.13

Cyclothymia (pronounced /ˌsaɪklə'θaɪmiə, ˌsɪklə-/) is a mood disorder. This disorder is a

milder form of bipolar II disorder consisting of recurrent mood disturbances between hypomania and dysthymic mood. A single episode of hypomania is sufficient to diagnose cyclothymic disorder; however, most individuals also have dysthymic periods. The diagnosis of cyclothymic disorder is never made when there is a history of mania or major depressive episode or mixed episode (as told in "Blueprints in Psychiatry" - "mood disorders"). The lifetime prevalence of cyclothymic disorder is 0.4-1%. The rate appears equal in men or women, though women more often seek treatment.

Contents

[hide]

Diagnostic criteria

DSM-IV-TR

- During the first two years of the disorder, the patient has not fulfilled enough criteria to qualify as having either bipolar disorder or major depressive disorder.
- Symptoms are present for at least two years: periods of hypomanic symptoms and periods of low mood that do not fulfill the criteria for major depressive disorder.
- The longest period the patient has been free of symptoms is two months.
- The disorder cannot be better explained as schizoaffective disorder, and it is not superimposed on schizophrenia, schizophreniform disorder, delusional disorder or psychotic disorder not otherwise specified.
- Symptoms are not directly caused by a general medical condition or the use of any substances such as prescription medicines.
- The symptoms cause the patient clinically significant distress or impair work, social or personal functioning.
- A person with this disorder may experience euphoric highs, boosts of energy and require less sleep in one phase, followed by a severe mood swings into a depressive state coupled with negativity & sadness for no particular reason.
- These mood swings are not as severe as bipolar I disorder or bipolar II disorder.
- Cyclothymia is to bipolar disorder as Dysthymia (a mild form of clinical depression) is to major depressive disorder.

ICD-10

A persistently unstable mood, involving many periods of mild depression and mild elation. This instability usually develops in late adolescence and follows a chronic course, although moods may be within norms for months at a time. Mood swings are usually perceived by

the individual as being unrelated to life events. The diagnosis is difficult to establish without a prolonged period of observation or an unusually good account of the individual's past behaviour. Because the mood swings are relatively mild and the episodes of mood elevation may be enjoyable, cyclothymia frequently fails to come to medical attention. In some cases this may be because the mood change, although present, is less prominent than cyclical changes in activity, self-confidence, sociability, or appetitive behaviour. If required, age of onset may be specified as early (in late teenage or the twenties) or later.

The essential feature is a persistent instability of mood, involving numerous periods of mild depression and mild elation, none of which has been sufficiently severe or prolonged to fulfill the criteria for bipolar disorder or recurrent depressive disorder. This implies that individual episodes of mood swings do not fulfill the criteria for any of the categories described under manic episode or major depressive episode.

Differential diagnosis

This disorder is common in the relatives of patients with bipolar disorder and some individuals with cyclothymia eventually develop bipolar disorder themselves. It may persist throughout adult life, cease temporarily or permanently, or develop into more severe mood swings meeting the criteria for bipolar disorder or recurrent depressive disorder in rare cases.

Causes

Cyclothymia appears to have a genetic contribution, which has been shown by a range of twin studies involving dizygotic (fraternal) and monozygotic (identical) twins. [1][2]

Psychosocial factors have also been implicated, for example stressful life events or living conditions, and interpersonal difficulties. In addition, some hypotheses posit that the hypomanic episodes have meaning in the context of a person seeking to achieve goals or to avoid depression. [*citation needed*]

Treatment

Treatment for cyclothymia can include a variety of cognitive behavioral therapy techniques. Prescription drugs such as lamotrigine, lithium, verapamil [3] and benzodiazepines are often used to treat cyclothymia.

See also

- Cyclothymic personality
- Dysthymia
- Euthymia
- Motivation
- Ultradian Bipolar Disorder

References

1. ^ AJ Giannini. The Biological Foundations of Clinical Psychiatry. New Hyde Park,NY.

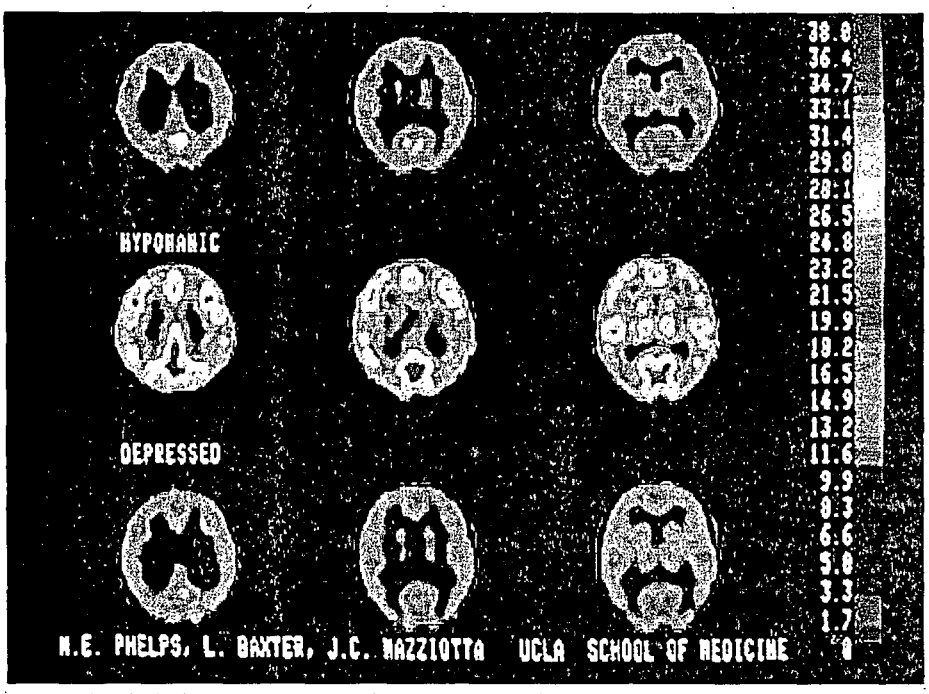
Medical Examination Publishing Co.,1983.
2. ^ Edvardsen J, Torgersen S, Røysamb E, *et al* (March 2008). "Heritability of bipolar spectrum disorders. Unity or heterogeneity?". *Journal of affective disorders* **106** (3): 229-40. doi:10.1016/j.jad.2007.07.001. PMID 17692389.
3. ^ AJ Giannini,WA Price. Verapamil in the treatment of mania. Journal of Clinical Pharmacology.24:400-401,1984.

External links

- Psychnet UK Cyclothymic Disorder information sheet
- Cyclothymia Symptoms from CounsellingResource.com
- Cyclothymia from Psycom.net
- Cyclothymia from McmanWeb
- What Is Cyclothymia? from Mental Health Matters
- Mental Health Matters: Cyclothymia from Mental Health Matters
- Cyclothymia Workbook from All About Depression
- Bipolar4all UK support site
- CyclothymiaCollective English language blog that connects to forum on Cyclothymia
- Cyclothymia : Through The Patient's Eyes useful course module

v · d · e **WHO ICD-10 mental and behavioral disorders (F · 290-319)** [show]

Exhibit D



Dr. Michael Phelps/Lewis Baxton/UCLA School of Medicine

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Exhibit

E

Drug Information Online
Drugs.com

Prozac

Generic Name: fluoxetine (floo OX e teen)
Brand names: *PROzac, PROzac Weekly, Rapiflux, Sarafem, Selfemra, PROzac Pulvules*

What is Prozac?

Prozac (fluoxetine) is a selective serotonin reuptake inhibitors (SSRI) antidepressant. Prozac affects chemicals in the brain that may become unbalanced and cause depression, panic, anxiety, or obsessive-compulsive symptoms.

Prozac is used to treat major depressive disorder, bulimia nervosa (an eating disorder) obsessive-compulsive disorder, panic disorder, and premenstrual dysphoric disorder (PMDD).

Prozac is sometimes used together with another medication called olanzapine (Zyprexa) to treat depression caused by bipolar disorder (manic depression). This combination is also used to treat depression after at least 2 other medications have been tried without successful treatment of symptoms.

Prozac may also be used for purposes not listed in this medication guide.

Important information about Prozac

Do not take Prozac together with pimozide (Orap), thioridazine (Mellaril), or a monoamine oxidase inhibitor (MAOI) such as furazolidone (Furoxone), isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Eldepryl, Emsam, Zelapar), or tranylcypromine (Parnate). A dangerous drug interaction could occur, leading to serious side effects.

You may have thoughts about suicide when you first start taking an antidepressant, especially if you are younger than 24 years old. Your doctor will need to check you at regular visits for at least the first 12 weeks of treatment with Prozac.

Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Tell your doctor right away if you become pregnant while taking this medication. Prozac may cause heart defects or serious lung problems in a newborn if you take the medication during pregnancy. However, you may have a relapse of depression if you stop taking your antidepressant. Do not start or stop taking Prozac during pregnancy without your doctor's advice.

Before taking Prozac

Do not take Prozac together with pimozide (Orap), thioridazine (Mellaril), or a monoamine oxidase inhibitor (MAOI) such as furazolidone (Furoxone), isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Eldepryl, Emsam, Zelapar), or tranylcypromine (Parnate). A dangerous drug interaction could occur, leading to serious side effects. You must wait at least 14 days after stopping an MAO inhibitor before you can take Prozac. You must wait 5 weeks after stopping Prozac before you can take thioridazine (Mellaril) or an MAOI.

Tell your doctor about all other antidepressants you take, especially Celexa, Cymbalta, Desyrel, Effexor, Lexapro, Luvox, Oleptro, Paxil, Pexeva, Symbyax, Viibryd, or Zoloft.

To make sure you can safely take Prozac, tell your doctor if you have any of these other conditions:

- cirrhosis of the liver;
- kidney disease;
- diabetes;
- glaucoma;
- seizures or epilepsy;
- bipolar disorder (manic depression); or
- a history of drug abuse or suicidal thoughts.

You may have thoughts about suicide while taking an antidepressant, especially if you are younger than 24 years old. Tell your doctor if you have worsening depression or suicidal thoughts during the first several weeks of treatment with Prozac, or whenever your dose is changed.

Your family or other caregivers should also be alert to changes in your mood or symptoms. Your doctor will need to check you at regular visits for at least the first 12 weeks of treatment.

FDA pregnancy category C. Tell your doctor right away if you become pregnant while taking Prozac. Fluoxetine may cause heart defects or serious lung problems in a newborn if you take the medication during pregnancy. However, you may have a relapse of depression if you stop taking your antidepressant. Do not start or stop taking Prozac during pregnancy without your doctor's advice. Fluoxetine can pass into breast milk and may harm a nursing baby. Do not use Prozac without telling your doctor if you are breast-feeding a baby. Do not give Prozac to anyone younger than 18 years old without a doctor's advice.

See also: Prozac information from Drugs.com pregnancy and breastfeeding warnings (in more detail)

How should I take Prozac?

Take Prozac exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label.

Your doctor may occasionally change your dose of Prozac to make sure you get the best results.

Do not crush, chew, break, or open an extended-release Prozac capsule. Swallow it whole. Breaking or opening the pill may cause too much of the drug to be released at one time.

Measure liquid medicine with a special dose measuring spoon or medicine cup, not with a regular table spoon. If you do not have a dose measuring device, ask your pharmacist for one.

It may take up to 4 weeks before your symptoms improve. Keep using Prozac as directed and tell your doctor if your symptoms do not improve after 4 weeks of treatment. Do not stop using Prozac suddenly, or you could have unpleasant withdrawal symptoms. Ask your doctor how to avoid withdrawal symptoms when you stop using Prozac.

To treat premenstrual dysphoric disorder, the usual dose of Prozac is once daily while you are having your period, or 14 days before you expect your period to start. Follow your doctor's instructions.

Store Prozac at room temperature away from moisture and heat.

What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

If you miss a dose of Prozac Weekly, take the missed dose as soon as you remember and take the next dose 7 days later. However, if it is almost time for the next regularly scheduled weekly dose, skip the missed dose and take the next one as directed. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose may cause nausea, vomiting, fever, sleepiness, rapid or uneven heartbeat, confusion, fainting, seizures, or coma.

What should I avoid while taking Prozac?

Avoid taking tryptophan while you are taking Prozac.

Drinking alcohol can increase certain side effects of Prozac. This medication may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

See also: Prozac information from Drugs.com and alcohol (in more detail)

Prozac side effects

Get emergency medical help if you have any of these signs of an allergic reaction to Prozac: skin rash or hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Call your doctor at once if you have a serious side effect while taking Prozac such as:

- severe blistering, peeling, and red skin rash;
- very stiff (rigid) muscles, high fever, sweating, fast or uneven heartbeats, tremors, overactive reflexes;
- nausea, vomiting, diarrhea, loss of appetite, feeling unsteady, loss of coordination; or
- headache, trouble concentrating, memory problems, weakness, confusion, hallucinations, fainting, seizure, shallow breathing or breathing that stops.

Less serious Prozac side effects may include:

- cold symptoms such as stuffy nose, sneezing, sore throat;
- drowsiness, dizziness, feeling nervous;
- mild nausea, upset stomach, constipation;
- increased appetite, weight changes;
- sleep problems (insomnia);
- decreased sex drive, impotence, or difficulty having an orgasm; or
- dry mouth.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also: Prozac information from Drugs.com side effects (in more detail)

What other drugs will affect Prozac?

Cold or allergy medicine, sedatives, narcotic pain medicine, sleeping pills, muscle relaxers, and medicine for seizures or anxiety can add to sleepiness caused by Prozac. Tell your doctor if you regularly use any of these medicines. Ask your doctor before taking a nonsteroidal anti-inflammatory drug (NSAID) for pain, arthritis, fever, or swelling. This includes aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve, Naprosyn, Naprelan, Treximet), celecoxib (Celebrex), diclofenac (Arthrotec, Cambia, Cataflam, Voltaren, Flector Patch, Pennsaid, Solareze), indomethacin (Indocin), meloxicam (Mobic), and others. Using an NSAID with Prozac may cause you to bruise or bleed easily.

Tell your doctor about all other medications you are using, especially:

- any other antidepressants such as amitriptyline (Elavil, Vanatrip, Limbitrol), escitalopram (Lexapro), imipramine (Tofranil), sertraline (Zoloft), and others;

- alprazolam (Xanax);
- clopidogrel (Plavix);
- clozapine (Clozaril, Fazaclo);
- flecainide (Tambocor);
- haloperidol (Haldol);
- vinblastine (Velban);
- a blood thinner such as warfarin (Coumadin, Jantoven);
- migraine headache medicine such as almotriptan (Axert), frovatriptan (Frova), sumatriptan (Imitrex, Treximet), naratriptan (Amerge), rizatriptan (Maxalt), or zolmitriptan (Zomig); or
- seizure medication such as phenytoin (Dilantin) or carbamazepine (Carbatrol, Equetro, Tegretol).

This list is not complete and other drugs may interact with Prozac. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor.

Where can I get more information?

- Your pharmacist can provide more information about Prozac.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Prozac only for the indication prescribed.
- Every effort has been made to ensure that the information provided by Cerner Multum, Inc. ('Multum') is accurate, up-to-date, and complete, but no guarantee is made to that effect. Drug information contained herein may be time sensitive. Multum information has been compiled for use by healthcare practitioners and consumers in the United States and therefore Multum does not warrant that uses outside of the United States are appropriate, unless specifically indicated otherwise. Multum's drug information does not endorse drugs, diagnose patients or recommend therapy. Multum's drug information is an informational resource designed to assist licensed healthcare practitioners in caring for their patients and/or to serve consumers viewing this service as a supplement to, and not a substitute for, the expertise, skill, knowledge and judgment of healthcare practitioners. The absence of a warning for a given drug or drug combination in no way should be construed to indicate that the drug or drug combination is safe, effective or appropriate for any given patient. Multum does not assume any responsibility for any aspect of healthcare administered with the aid of information Multum provides. The information contained herein is not intended to cover all possible uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the drugs you are taking, check with your doctor, nurse or pharmacist.

Exhibit F

Drug Information Online
Drugs.com

Prozac Side Effects

Generic Name: *fluoxetine,fluoxetine hydrochloride*

Please note - some side effects for Prozac may not be reported. Always consult your doctor or healthcare specialist for medical advice. You may also report side effects to the FDA.

Side Effects of Prozac - for the Consumer

Prozac

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome when using Prozac:

Abnormal dreams; anxiety; decreased sexual desire or ability; diarrhea; dizziness; drowsiness; dry mouth; flu-like symptoms (eg, fever, chills, muscle aches); flushing; increased sweating; loss of appetite; nausea; nervousness; runny nose; sore throat; stomach upset; trouble sleeping; weakness; yawning.

Seek medical attention right away if any of these SEVERE side effects occur when using Prozac:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; unusual hoarseness); bizarre behavior; black or bloody stools; chest pain; confusion; decreased concentration; decreased coordination; exaggerated reflexes; excessive sweating; fainting; fast or irregular heartbeat; fever, chills, or sore throat; hallucinations; increased hunger, thirst, or urination; joint or wrist aches or pain; memory loss; new or worsening agitation, panic attacks, aggressiveness, impulsiveness, irritability, hostility, exaggerated feeling of well-being, restlessness, or inability to sit still; persistent or severe ringing in the ears;persistent, painful erection; red, swollen, blistered, or peeling skin; seizures; severe or persistent anxiety, trouble sleeping, or weakness; severe or persistent nausea, vomiting, diarrhea, or headache; significant weight loss; stomach pain; suicidal thoughts or attempts; tremor; trouble urinating; unusual bruising or bleeding; unusual or severe mental or mood changes; unusual swelling; unusual weakness; vision changes; worsening of depression.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the Guide to Reporting Problems to FDA.

Prozac Weekly Delayed-Release Capsules

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome when using Prozac Weekly Delayed-Release Capsules:

Abnormal dreams; anxiety; decreased sexual desire or ability; diarrhea; dizziness; drowsiness; dry mouth; flu-like symptoms (eg, fever, chills, muscle aches); flushing; increased sweating; loss of appetite; nausea; nervousness; runny nose; sore throat; stomach upset; trouble sleeping; weakness; yawning.

Seek medical attention right away if any of these SEVERE side effects occur when using Prozac Weekly Delayed-Release Capsules:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; unusual hoarseness); bizarre behavior; black or bloody stools; chest pain; confusion; decreased concentration; decreased coordination; exaggerated reflexes; excessive sweating; fainting; fast or irregular heartbeat; fever, chills, or sore throat; hallucinations; increased hunger, thirst, or urination; joint or wrist aches or pain; memory loss; new or worsening agitation, panic attacks, aggressiveness, impulsiveness, irritability, hostility, exaggerated feeling of well-being, restlessness, or inability to sit still; persistent or severe ringing in the ears; persistent, painful erection; red, swollen, blistered, or peeling skin; seizures; severe or persistent anxiety, trouble sleeping, or weakness; severe or persistent nausea, vomiting, diarrhea, or headache; significant weight loss; stomach pain; suicidal thoughts or attempts; tremor; trouble urinating; unusual bruising or bleeding; unusual or severe mental or mood changes; unusual swelling; unusual weakness; vision changes; worsening of depression.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the Guide to Reporting Problems to FDA.

Prozac Solution

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome when using Prozac Solution:

Abnormal dreams; anxiety; decreased sexual desire or ability; diarrhea; dizziness; drowsiness; dry mouth; flu-like symptoms (eg, fever, chills, muscle aches); flushing; increased sweating; loss of appetite; nausea; nervousness; runny nose; sore throat; stomach upset; trouble sleeping; weakness; yawning.

Seek medical attention right away if any of these SEVERE side effects occur when using Prozac Solution:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; unusual hoarseness); bizarre behavior; black or bloody stools; chest pain; confusion; decreased concentration; decreased coordination; exaggerated reflexes; excessive sweating; fainting; fast or irregular heartbeat; fever, chills, or sore throat; hallucinations; increased hunger, thirst, or urination; joint or wrist aches or pain; memory loss; new or worsening agitation, panic attacks, aggressiveness, impulsiveness, irritability, hostility, exaggerated feeling of well-being, restlessness, or inability to sit still; persistent or severe ringing in the ears;persistent, painful erection; red, swollen, blistered, or peeling skin; seizures; severe or persistent anxiety, trouble sleeping, or weakness; severe or persistent nausea, vomiting, diarrhea, or headache; significant weight loss; stomach pain; suicidal thoughts or attempts; tremor; trouble urinating; unusual bruising or bleeding;

unusual or severe mental or mood changes; unusual swelling; unusual weakness; vision changes; worsening of depression.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the Guide to Reporting Problems to FDA.

Top

Side Effects by Body System - for Healthcare Professionals

Gastrointestinal

A study of 26,005 antidepressant users has reported 3.6 times more upper GI bleeding episodes with the use of SSRIs relative to the population who did not receive antidepressant medications. Upper gastrointestinal tract bleeding was observed in 3.9 times more frequently in patients receiving fluoxetine. (Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that bleeding at other sites may also be potentiated.)

Gastrointestinal side effects have frequently included nausea (15% to 21%) and diarrhea (12%). Dry mouth, constipation, dyspepsia, stomatitis, and upper gastrointestinal bleeding have also been reported.

Nervous system

Nervous system side effects including headache, anxiety, nervousness, insomnia, drowsiness, sedation, tremor, dizziness, jitteriness, and fatigue have all been reported. The reported incidence of each of these effects ranges between 4% and 20% of treated patients. Cases of akathisia, neuromuscular twitching, tics, myoclonus, migraines, sleep abnormalities, dyskinesia, acute dystonic reactions, worsening of Parkinson's disease, seizures, stuttering, paresthesias, and cognitive dysfunction have also been reported. Balance disorder and bruxism have also been reported. Postmarketing experience has included memory impairment.

Cases of the neuroleptic malignant syndrome occurring in patients started on fluoxetine have been reported.

One retrospective study of 23 outpatients with Parkinson's disease treated with 40 mg of fluoxetine a day reported that three patients experienced worsening of parkinsonism, two patients experienced improvement of parkinsonism, and 18 patients experienced no change. Another small study reported a series of four patients who experienced worsening of parkinsonism during treatment with fluoxetine.

A number of case reports have implicated fluoxetine in causing seizures. The manufacturer reports that, during premarketing testing, 12 out of 6000 patients experienced convulsions.

A case of dose-dependent exacerbation of preexisting, mild restless legs syndrome (which ultimately required discontinuation of fluoxetine) has been reported.

Nearly all selective serotonin reuptake inhibitors, mixed serotonin/norepinephrine reuptake inhibitors, and tricyclic antidepressants cause sleep abnormalities to some extent. These antidepressants have marked dose-dependent effects on rapid eye movement (REM) sleep, causing reductions in the overall amount of REM sleep over the night and delays the first entry into REM sleep (increased REM sleep onset latency (ROL)), both in healthy subjects and depressed patients. The antidepressants that increase serotonin function appear to have the greatest effect on REM sleep. The reduction in REM sleep is greatest early in treatment, but gradually

returns towards baseline during long-term therapy; however, ROL remains long. Following discontinuation of therapy the amount of REM sleep tends to rebound. Some of these drugs (i.e., bupropion, mirtazapine, nefazodone, trazodone, trimipramine) appear to have a modest or minimal effect on REM sleep.

Psychiatric

The reported association between fluoxetine therapy and the development of suicidal ideation is controversial. The 1991 meta-analysis of controlled trials (which was sponsored by the manufacturer of fluoxetine) reported six suicidal acts occurring in a total of 1763 patients treated with fluoxetine. The frequency of suicidal acts was 0.3% and was similar to the frequency reported for placebo (0.2%) and tricyclic antidepressant therapy (0.4%).

Several cases of fluoxetine abuse have been reported in patients with a history of stimulant abuse.

Additionally, several cases of panic attacks and severe nightmares have been associated with fluoxetine therapy.

Psychiatric side effects including hypomania, mania, transient psychosis, development of obsessive-compulsive symptoms, paranoid reaction, delusions, agitation, and a depersonalization syndrome have been reported. A number of reports have suggested that fluoxetine may be associated with the development of suicidal ideation. However, a meta-analysis of controlled studies has suggested that such an association may not exist. A retrospective study of suicidal ideation in 294 patients treated with fluoxetine for depression compared to other patients treated with a variety of therapeutic agents for depression has also suggested that an association between fluoxetine and increased risk of suicidal ideation may not exist.

Other

Nearly all selective serotonin reuptake inhibitors, mixed serotonin/norepinephrine reuptake inhibitors, and tricyclic antidepressants cause sleep abnormalities to some extent. These antidepressants have marked dose-dependent effects on rapid eye movement (REM) sleep, causing reductions in the overall amount of REM sleep over the night and delays the first entry into REM sleep (increased REM sleep onset latency (ROL)), both in healthy subjects and depressed patients. The antidepressants that increase serotonin function appear to have the greatest effect on REM sleep. The reduction in REM sleep is greatest early in treatment, but gradually returns towards baseline during long-term therapy; however, ROL remains long. Following discontinuation of therapy the amount of REM sleep tends to rebound. Some of these drugs (i.e., bupropion, mirtazapine, nefazodone, trazodone, trimipramine) appear to have a modest or minimal effect on REM sleep.

Side effects on sleep have been reported and, in addition to insomnia, include vivid dreaming and an increase in the number of eye movements during non REM sleep.

General

Very rarely, the anorexic effects of fluoxetine have resulted in dramatic and dangerous reductions in body weight. One study of 20 non depressed obese women receiving 60 mg of fluoxetine a day indicated that the drug increased resting energy expenditure and basal body temperature. The author also notes the theory that a higher basal temperature preceding a meal could limit food consumption.

One study has reported that while the initial four weeks of fluoxetine therapy was associated with modest weight loss, weight gain for patients taking fluoxetine for longer periods was not different from the weight gain of control subjects (and was believed to be related to recovery from depression).

General side effects including anorexia (9%) have been reported.

Genitourinary

Genitourinary side effects including sexual dysfunction have been reported. The manufacturer has reported sexual dysfunction side effects at rate of 2%. However, some studies have reported sexual dysfunction in 7.8% to 34% of patients. Specific problems reported include male and female anorgasmia, decreased libido, penile anesthesia, vaginal anesthesia, ejaculatory dysfunction, and impotence. Gynecological bleeding, dysuria and micturition disorder have also been reported. It has been reported that symptoms of sexual dysfunction occasionally persist after discontinuation of fluoxetine treatment.

Clitoral enlargement and prolonged penile erection have been reported.

Cases of improved male sexual function in patients with erectile dysfunction have been reported. Sexual obsessions have also been reported.

Cardiovascular

One placebo-controlled study has suggested that fluoxetine has no effects on intraventricular conduction. Other case reports have suggested that fluoxetine may rarely provoke dysrhythmias. Other conflicting case reports have suggested that fluoxetine may have a propensity to provoke and alleviate vasoconstriction. Several cases of unexpected death occurring shortly after initiation of fluoxetine therapy have been reported in elderly patients with multiple medical problems.

In one case report, QTc prolongation and torsades de pointes developed in an elderly woman 6 months after starting therapy with fluoxetine 20 mg daily. The QTc interval returned to normal following discontinuation of fluoxetine. Four additional cases suggesting fluoxetine associated QTc prolongation or torsades de pointes have been reported.

Cardiovascular side effects including bradycardia have been reported to occur in controlled studies of patients treated with fluoxetine. Several cases of bradycardia- induced syncope have also been reported. Several cases of QTc prolongation or torsades de pointes have been reported in association with fluoxetine treatment. Hypotension has also been reported.

Hematologic

Hematologic side effects include case reports which have suggested that fluoxetine may interfere with platelet function. Petechiae, increased bleeding times, epistaxis, and gastrointestinal hemorrhage have been reported rarely in association with fluoxetine therapy.

Endocrine

Endocrine side effects include case reports which have suggested that fluoxetine may rarely result in the development of the syndrome of inappropriate secretion of antidiuretic hormone (particularly in elderly patients).

Cases of increased serum prolactin and resumption of menses and ovulation have been reported in patients taking fluoxetine.

Dermatologic

Dermatologic side effect including severe hair loss, psoriasis, excessive sweating, and cutaneous hypersensitivity reactions have been reported to occur in association with fluoxetine therapy. Erythema multiforme and toxic epidermal necrolysis have been reported rarely. Alopecia has also been reported.

Approximately 3% of treated patients have been reported to develop a skin reaction.

Ocular

Ocular side effects have included a case report which suggested that fluoxetine may provoke reversible narrow-angle glaucoma. In one study of 20 patients, all patients showed a significant increase in intraocular pressure 2 hours after oral administration of fluoxetine.

Respiratory

Respiratory side effects include a case report that suggested fluoxetine may provoke interstitial pulmonary damage. Another case report described a patient, receiving fluoxetine who developed progressive dyspnea, lung infiltrates, and restrictive lung disease. Pathologic findings were consistent with hypersensitivity pneumonitis. Associated pulmonary phospholipidosis was also noted.

Hypersensitivity

Hypersensitivity side effects involving rash, fever, lymphadenopathy, and arthralgias have been reported in association with fluoxetine use.

Hypersensitivity reactions generally require discontinuation of fluoxetine. Eli Lilly has disclosed 96 reports of serum sickness-like reactions occurring out of 15 million patients treated with fluoxetine.

Immunologic

Immunologic side effects including cases of reactivation of herpes simplex virus infection have been reported in patients treated with fluoxetine.

Hepatic

Hepatic side effects including five cases of hepatotoxicity have been reported in association with fluoxetine therapy. Asymptomatic increases in liver enzyme values have been reported in 0.5% of patients receiving long term fluoxetine therapy.

Musculoskeletal

In one study using the healthcare data from the providence of Ontario, Canada reviewing 8,239 patients treated for hip fractures, the adjusted odds ratio for hip fracture was 2.4 for exposure to selective serotonin reuptake inhibitors (including fluoxetine, fluvoxamine, paroxetine, and sertraline), compared to participants who had no exposure to antidepressants.

Musculoskeletal side effects may include an increased risk for hip fractures.

Other

Other side effects include a withdrawal type reaction. In one retrospective chart review of 352 patients who were supervised during tapering and discontinuation from serotonin reuptake inhibitor therapy, dizziness, lethargy,

paresthesia, nausea, vivid dreams, irritability, and lowered mood were the most common symptoms reported. Patients with at least on qualitatively new symptom were defined in the fluoxetine group at a rate of 1.5%.

Metabolic

Numerous cases of hyponatremia have been reported following treatment with a selective serotonin reuptake inhibitor (SSRI). Risk factors for the development of SSRI associated hyponatremia including advanced age, female gender, concomitant use of diuretics, low body weight, and lower baseline serum sodium levels have been identified. Hyponatremia tends to develop within the first few weeks of treatment (range 3 to 120 days) and typically resolves within 2 weeks (range 48 hours to 6 weeks) after therapy has been discontinued with some patients requiring treatment. The proposed mechanism for the development of hyponatremia involves the syndrome of inappropriate secretion of antidiuretic hormone (SIADH) via release of antidiuretic hormone.

Metabolic sides effects including hyponatremia have been reported in patients receiving fluoxetine.

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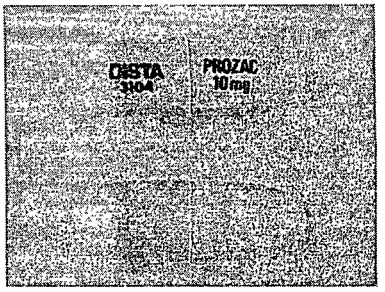
Exhibit G

PROZAC ORAL CAPSULE 10 MG



It is a(n) OBLONG CAPSULE.
It is GREEN.
It says 'DISTA 3104' on one side and 'PROZAC 10 mg' on the other side.
Other characteristics include: Black ink.

May Cause Drowsiness. Taking This Medicine Alone Or With Alcohol May Lessen Your Ability To Drive Or Perform Hazardous Tasks.

Warning: Do Not Use If You Are Breastfeeding. Consult Your Doctor Or Pharmacist.

Do Not Take Other Medicines Without Checking With Your Doctor Or Pharmacist.

Read The Medication Guide That Comes With This Medicine.

Take Or Use This Medicine Exactly As Directed. Do Not Skip Doses Or Discontinue Unless Directed By Your Doctor.

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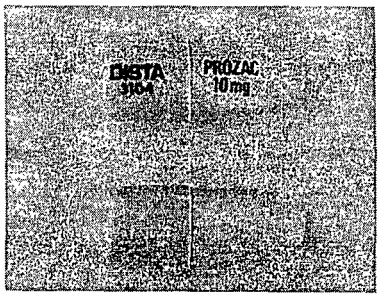

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GENERIC NAME: FLUOXETINE (floo-OX-e-teen)

COMMON USES: This medicine is a selective serotonin reuptake inhibitor (SSRI) used for treating depression or obsessive-compulsive disorder (OCD) in adults and children. It is used to treat bulimia nervosa and panic disorder in adults. It may also be used for other conditions as determined by your doctor.

BEFORE USING THIS MEDICINE: WARNING: Antidepressants may increase the risk of suicidal thoughts or actions in children, teenagers, and young adults. However, depression and certain other mental problems may also increase the risk of suicide. Talk with the patient's doctor to be sure that the benefits of using this medicine outweigh the risks. Family and caregivers must closely watch patients who take this medicine. It is important to keep in close contact with the patient's doctor. Tell the doctor right away if the patient has symptoms like worsened depression, suicidal thoughts, or changes in behavior. Discuss any questions with the patient's doctor. Some medicines or medical conditions may interact with this medicine. **INFORM YOUR DOCTOR OR PHARMACIST** of all prescription and over-the-counter medicine that you are taking. **DO NOT TAKE THIS MEDICINE** if you are taking or have taken linezolid, a monoamine oxidase inhibitor (MAOI) (eg, phenelzine), selegiline, or St. John's wort within the last 14 days. **DO NOT TAKE THIS MEDICINE IF** you are taking a fenfluramine derivative (eg, dexfenfluramine), an H1 antagonist (eg, astemizole, terfenadine), nefazodone, pimozide, a serotonin norepinephrine reuptake inhibitor (SNRI) (eg, venlafaxine), another **SSRI** (eg, paroxetine), sibutramine, thioridazine, or tryptophan. **ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION** may be needed if you are taking anorexiants (eg, phentermine), metoclopramide, serotonin 5-HT1 receptor agonists (eg, sumatriptan), trazodone, anticoagulants (eg, warfarin), aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen), diuretics (eg, furosemide, hydrochlorothiazide), tramadol, cyclobenzaprine, **HIV** protease inhibitors (eg, ritonavir), cyproheptadine, aripiprazole, benzodiazepines (eg, alprazolam), beta-blockers (eg, propranolol), carbamazepine, clozapine, dextromethorphan, digoxin, flecainide, haloperidol, hydantoins (eg, phenytoin), lithium, norepinephrine reuptake inhibitors (eg, atomoxetine), phenothiazines (eg, chlorpromazine), propafenone, risperidone, tricyclic antidepressants (eg, amitriptyline), vinblastine, or methylene blue. **DO NOT START OR STOP** any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including if you have a history of seizures, heart problems, liver problems, severe kidney problems, stomach or bowel bleeding, diabetes, metabolism problems, narrow-angle glaucoma or risk for narrow-angle glaucoma, allergies, pregnancy, or breast-feeding. Tell your doctor if you or a family member has a history of bipolar disorder (manic-depression), other mental or mood problems, suicidal thoughts or attempts, or alcohol or substance abuse. Tell your doctor if you are dehydrated, have low blood sodium levels, drink alcohol, or if you will be having electroconvulsive therapy (ECT). Contact your doctor or pharmacist if you have any questions or concerns about using this medicine.

HOW TO USE THIS MEDICINE: Follow the directions for taking this medicine provided by your doctor. This medicine comes with a **MEDICATION GUIDE** approved by the **U.S.** Food and Drug Administration. Read it carefully each time you refill this medicine. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. **TAKE THIS MEDICINE** with or without food. **STORE THIS MEDICINE** at room temperature, between 59 and 86 degrees F (15 and 30 degrees C) away from heat, moisture, and light. Do not store in the bathroom. **KEEP THIS MEDICINE** out of the reach of children and away from pets. Taking this medicine at the same time each day will help you remember to take it. Continue to take this medicine even if you feel well. Do not miss any doses. **DO NOT SUDDENLY STOP TAKING THIS MEDICINE** without checking with your doctor. Side effects may occur. They may include mental or mood changes, numbness or tingling of the skin, dizziness, confusion, headache, trouble sleeping, or unusual tiredness. You will be closely monitored when you start this medicine and whenever a change in dose is made. **IF YOU MISS A DOSE** of this medicine, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

CAUTIONS: DO NOT USE THIS MEDICINE IF you are allergic to any ingredient in this medicine. **THIS MEDICINE MAY CAUSE DROWSINESS OR DIZZINESS.** These effects may be worse if you take it with alcohol or certain medicines. Take this medicine with caution. **DO NOT DRIVE OR PERFORM OTHER POSSIBLY UNSAFE TASKS** until you know how you react to it. Check with your doctor before you drink alcohol or use medicines that may cause drowsiness while

you are taking this medicine; it may add to their effects. Ask your pharmacist if you have questions about which medicines may cause drowsiness. Do **NOT** take more than the recommended dose, change your dose, or take this medicine for longer than prescribed without checking with your doctor. **SEROTONIN SYNDROME** is a possibly fatal syndrome that can be caused by this medicine. Your risk may be greater if you take this medicine with certain other medicines (eg, "triptans", MAOIs). Symptoms may include agitation; confusion; hallucinations; coma; fever; fast or irregular heartbeat; tremor; excessive sweating; and nausea, vomiting, or diarrhea. Contact your doctor at once if you have any of these symptoms. **NEUROLEPTIC MALIGNANT SYNDROME** (NMS) is a possibly fatal syndrome that can be caused by this medicine. Symptoms may include fever; stiff muscles; confusion; abnormal thinking; fast or irregular heartbeat; and sweating. Contact your doctor at once if you have any of these symptoms. **IF YOUR DOCTOR TELLS YOU TO STOP TAKING THIS MEDICINE,** you will need to wait for several weeks before beginning to take certain other medicines (eg, MAOIs, nefazodone, thioridazine). Ask your doctor when you should start to take your new medicines after you have stopped taking this medicine. **THIS MEDICINE MAY RARELY CAUSE** a prolonged, painful erection. This could happen even when you are not having sex. If this is not treated right away, it could lead to permanent sexual problems such as impotence. Contact your doctor right away if this happens. **BEFORE YOU BEGIN TAKING ANY NEW MEDICINES,** either prescription or over-the-counter, check with your doctor or pharmacist. **DO NOT TAKE THIS MEDICINE** if you are also taking Sarafem or Symbyax. Use this medicine with caution in the **ELDERLY;** they may be more sensitive to its effects. Caution is advised when using this medicine in **CHILDREN;** they may be more sensitive to its effects, especially increased risk of suicidal thoughts or actions. This medicine may cause weight changes. **CHILDREN** and teenagers may need regular weight and growth checks while they take this medicine. **FOR WOMEN: THIS MEDICINE MAY CAUSE HARM** to the fetus. If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using this medicine while you are pregnant. **THIS MEDICINE IS FOUND** in breast milk. **DO NOT BREAST-FEED** while taking this medicine. **DIABETES PATIENTS:** This medicine may affect your blood sugar. Check blood sugar levels closely. Ask your doctor before you change the dose of your diabetes medicine.

POSSIBLE SIDE EFFECTS: SIDE EFFECTS that may occur while taking this medicine include abnormal dreams; anxiety; diarrhea; dizziness; drowsiness; dry mouth; flu-like symptoms (eg, fever, chills, muscle aches); flushing; increased sweating; loss of appetite; nausea; nervousness; runny nose; sore throat; stomach upset; trouble sleeping; weakness; or yawning. If they continue or are bothersome, check with your doctor. **THIS MEDICINE MAY CAUSE** decreased sexual desire or ability. This has occasionally been reported to continue after treatment has been stopped. Discuss any questions or concerns with your doctor. **CONTACT YOUR DOCTOR IMMEDIATELY** if you experience bizarre behavior; black or bloody stools; chest pain; confusion; difficulty concentrating; exaggerated reflexes; excessive sweating; fainting; fast or irregular heartbeat; fever, chills, or sore throat; hallucinations; increased hunger, thirst, or urination; joint or wrist aches or pain; loss of coordination; memory loss; new or worsening agitation, panic attacks, aggressiveness, impulsiveness, irritability, hostility, exaggerated feeling of well-being, restlessness, or inability to sit still; persistent or severe ringing in the ears; persistent, painful erection; red, swollen, blistered, or peeling skin; seizures; severe or persistent anxiety, trouble sleeping, or weakness; severe or persistent nausea, vomiting, diarrhea, or headache; significant weight loss; stomach pain; suicidal thoughts or attempts; tremor; trouble urinating; unusual bruising or bleeding; unusual or severe mental or mood changes; unusual swelling; vision changes; or worsening of depression. **AN ALLERGIC REACTION** to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; or unusual hoarseness. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. You may report side effects to **FDA** at 1-800-FDA-1088.

OVERDOSE: IF OVERDOSE IS SUSPECTED, contact your local poison control center or emergency room immediately. Symptoms may include coma; confusion; delirium; difficult breathing; fainting; fast, slow, or irregular heartbeat; fever; seizures; severe or persistent dizziness, drowsiness, nausea, or vomiting; tremor.

ADDITIONAL INFORMATION: DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. **DO NOT USE THIS MEDICINE** for other health conditions. **IF YOU WILL BE USING THIS MEDICINE FOR AN EXTENDED PERIOD OF TIME,** be sure to obtain necessary refills before your supply runs out. **CHECK WITH YOUR PHARMACIST** about how to dispose of unused medicine.

Issue Date: August 8, 2012