#### STATE OF PLORIDA COMMISSION ON ETHICS P. O. DRAWER 15709, TALLAHASSEE, PLORIDA 32517-5709 COMPLAINT

#### 1. PERSON BRINGING COMPLAINT:

Name Josefina Perez \_\_\_\_\_ Telephone Number: (305) 345-8940

Address: P.O. Box 343445

City: Florida City County: Miami-Dade Zip Code: 33034

#### 2. PERSON AGAINST WHOM COMPLAINT IS BROUGHT:

Current or former public officer, public employee, candidate, or lobbyist - please use one complaint form for each person you wish to complain against:

Name: Rajiv Tandon Telephone Number: (850) 663-7192

Address 1317 Winewood Boulevard, Building 6, Room 235

City: \_\_\_\_\_ County: \_\_\_\_\_ Zip Code: \_\_\_\_\_\_ Zip Co

Title of office or position held or sought <u>DCF</u> - Chief of Psychiatry

#### 3. STATEMENT OF FACTS:

Please explain your complaint fully, either on the reverse side of this form or on additional sheets, providing a detailed description of the facts and the actions of the person named above. Include relevant dates and the names and addresses of persons whom you believe may be witnesses. If you believe that a particular provision of Article II, Section 8, Florida Constitution (the Sunshine Amendment) or of Part III, Chapter 118, Florida Statutes (the Code of Ethics for Public Officers and Employees) has been violated, please state the specific section(s). Please do not attach copies of lengthy documents; if they are relevant, your description of them will suffice. Also, please do not submit video tapes or audio tapes.

#### . OATH

I, the person bringing this complaint, do depose on oath or affirmation and say that the facts set forth in the foregoing complaint and attachments thereto are true and correct to the best of my knowledge and belief.

CE FORM SQ .-- EFF. 4/2008

### STATE OF FLORIDA

Sworn to (or affirmed) and subscribed before me ୮୯୯ day of \_ Ch b mi this ose Fina Perez <u>20 0 S</u> by\_i] (name of person making statement) Sug DLL (Signature of Notary Public - State of Florida) ~OMANDO ourdes. med Name of Notary Public) (Print, Type, or Shu Personally Known \_\_\_\_\_ OR Produced Identification Type of Identification Produced: Flo-LOLADES & GUNNEO 1993 DN # DD 66510 W 601 50 JAN 2011

April 14, 2008

To Whom It May Concern:

In response to the following article, "Drug research: to test or to tout?" by Robert Farley, published in the St. Petersburg Times, Sunday, April 13, I am filing this complaint with the Florida Commission on Ethics.

Rajiv Tandon rigged a one-sided Florida consensus panel by inviting only members in favor of much higher priced atypical antipsychotics.

This one-sided approach ignored the conclusions of major, independent national government studies, one U.S., one British, which established that the atypicals were no safer or more effective than the older drugs. Even the FDA stated "We would consider any advertisement or promotion labeling for Risperdal false, misleading or lacking fair balance...if there is a presentation of data that conveys the impression that (Risperdal) is superior to haloperidol (generic for Haldol) or nay other marketed antipsychotic drug product with regard to safety or effectiveness."

Setting treatment guidelines, favoring atypicals, ignores science and costs taxpayers and patients dearly: "The new drugs can cost 20 times as much as the old, so tax payers pay a small fortune in Medicaid expenses. In Florida alone in the past five years, taxpayers spent more than \$1.1 billion on the new antipsychotic drugs." These atypicals have serious side effects such as rapid weight gain, diabetes, even death.

Tandon, who is unlicensed to practice medicine in the state of Florida, misused his public position to secure a special benefit for specific atypical pharmaceutical companies who have employed him in the past. Tandon's orchestration of this panel benefits atypical makers and conflicts with his duty as a Florida public servant. Tandon's unwise fiscal actions contributed to the diversion of millions of Medicaid dollars to the atypical pharmaceutical makers. A casual search on the internet reveals he has worked for all the atypical makers.

Your response to this complaint will reflect on how the state of Florida is handling unethical acts of misconduct and the demise of this particular individual and those who follow in this path of choice. It is the duty of this commission to investigate and act accordingly. To ensure that individuals, such as Mr. Tandon are not representing the state of Florida, nor to stand behind any form of decision making with regards to outcomes of great importance, during a time of severe shortages in our budget, by rigging outcomes that cost the state double or perhaps triple the amount in expenditures without justification and necessity.

Your prompt response to this inquiry is greatly appreciated.

Sincerely,

Josefina Perez PO Box 343445 Florida City, FL 33034 (305) 345-8940 Albert P. Massey, III Chair Charles Lydecker Vice Chair Michael W. Brown Linda D. Counhan Cheryl Forehilli Larry R. Handfield Latour "LT" Lafferty Roy Rogers Thomas P. Scarritt, Jr.



State of Florida COMMISSION ON ETHICS P.O. Drawer 15709 Tellahassee, FL 32317-5789

3699 Maclay Blvd., South, Suite 201 Tallahassee, FL 32312 Philip Claypool Executive Director

Virlindia Doss Deputy Executive Director

(850) 488-7864 Phone (850) 488-3077 (FAX) www.ethics.state.fl.us

CERTIFIED MAIL

#### April 22, 2008

Mr. Rajiv Tandon 1317 Winewood Blvd., Bldg. 6, Rm. 235 Tallahassee, FL 32399

# Confidentia

**RETURN RECEIPT REOUESTED** 

#### RE: Complaint No. 08-055, In re RAJIV TANDON

Dear Mr. Tandon:

The above-captioned complaint, recently received in the office of the Commission on Ethics, is being transmitted to you pursuant to the requirements of Section 112.324, Florida Statutes. This office will forward all future correspondence in this matter to you at the above-listed mailing address unless otherwise notified of a change in your address. This transmittal is a routine administrative requirement which should not be construed as an approval, disapproval, or judgment of the complaint, either as to its terminology or merits.

Please note that this complaint, as well as all of the Commission's proceedings and records relating to the complaint, remain confidential either until you make a written request to the Commission that such records be made public or until the complaint reaches a stage in the Commission's proceedings where it becomes public. Unless we receive a written waiver of confidentiality from you, our office is not free to release any documents or to comment on this complaint to members of the public or the press, so long as the complaint remains in a confidential stage. The Commission's procedures on confidentiality do not govern the actions of the complainant or the respondent.

The following information is submitted to aid you in understanding the three procedural stages which a complaint may go through under the Commission's rules. The first stage in our complaint process is a determination of whether the allegations of the complaint are legally sufficient, that is, whether they indicate a possible violation of any law over which the Commission has jurisdiction. If the complaint is found not to be legally sufficient, the Commission will order that the complaint be dismissed without investigation and all records relating to the complaint will become public at that time. RUIV TANDON Page 2 April 22, 2008

If the complaint is found to be legally sufficient, a preliminary investigation will be undertaken by the investigative staff of the Commission. The second stage of the Commission's proceedings involves the preliminary investigation of the complaint and a decision by the Commission of whether there is probable cause to believe that there has been a violation of any of the ethics laws. If the complaint is investigated, you and the complainant will be given an opportunity to speak with the investigator. You also will be sent a copy of our investigative report prior to any action by the Commission and will be given the opportunity to respond to the report in writing. If the Commission finds that there is no probable cause to believe that there has been a violation of the ethics laws, the complaint will be dismissed and will become public at that time.

If the Commission finds that there is probable cause to believe there has been a violation of the ethics laws, the complaint becomes public and enters the third stage of proceedings, which requires that the Commission decide whether the law actually was violated and, if so, whether a penalty should be recommended. At this stage, you have the right to request a public hearing (trial) at which evidence would be presented, or the Commission may order that such a hearing be held. Public hearings usually are held in or near the area where the alleged violation occurred.

You will be notified of the Commission's decisions at each stage and are entitled to be represented by legal counsel during out proceedings. Upon written request, documents and notices regarding the complaint will be provided to the attorney.

If you are unfamiliar with the ethics laws and the Commission's responsibilities, I encourage you to access our website at <u>www.ethics.state.fl.us</u>, where you will find publications, rules, and other information. If there are any questions concerning this complaint or the procedures being followed by the Commission, please feel free to contact Ms. Kaye Starling, our Complaint Coordinator, at (850) 488-7864.

Sincerely,

Philip Olaypool // Executive Director

Enclosure

CC;

Ms. Josefina Perez, Complainant



#### reports

guidelines that decreed atypicals should be the drugs of choice.

Despite the FDA ostensibly reining them in, the drug companies remade the marketplace.

Atypicals have become the overwhelming drug of choice, and not just for schizophrenia and bipolar disorder, the crippling illnesses they were approved for. Doctors commonly prescribe them to treat anxiety, depression and ADHD in children. They're even given as sleep aids.

The new drugs can cost 20 times as much as the old, so taxpayers pay a small fortune in Medicaid expenses. In Florida alone in the past five years, taxpayers spent more than \$1.1-billion on the new antipsychotic drugs.

The drug companies, meantime, enjoy billions in profits.

...

Allen Jones knew the instant he was destined to be a whistle-blower. He says it was when his boss told him: "Quit being a salmon. Quit swimming against the stream with the pharmaceutical case."

It was a fluke that the case landed on his desk, and it was a fluke that he was even working in the office of the Inspector General in Pennsylvania.

Twice divorced, a single dad with custody of his kids, he had been swinging a hammer, doing rehab work on houses and flipping them. He figured signing on with the state would give him financial security and early retirement.

But life has a way of veering from script, and in 2002, he happened to draw a case where the state's chief pharmacist reportedly was earning money on the side — from a pharmaceutical company.

Jones learned that the chief pharmacist headed a government panel that would decide which drugs doctors should reach for first to treat severe mental illnesses in Pennsylvania. All of the drugs being touted as front-line were brand new, patented, and therefore exceptionally expensive. Yet some experts that Jones talked to said the new drugs were no better than the old ones.

"It didn't pass the smell test," he said. "There was too much opportunity for fraud."

He suspected that pharmaceutical companies promoting their new drugs were "buying off" state officials in positions to influence the prescription practices of doctors across Pennsylvania. Taxpayers were paying the freight for these high-priced drugs.

That's when Jones says his boss told him not to play the part of the salmon. Drop it, the politicians will never stand for a real investigation: "I was told point-blank, 'These pharmaceutical companies write checks on both sides of the aisle.'"

Jones ended up taking his concerns to the press. It wasn't long before a security guard escorted him from the building and into the ranks of the unemployed.

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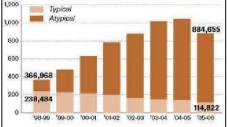
The idea of establishing state guidelines for prescription practices originated in Texas in 1996, under an ungainly name:

The Texas Medications Algorithm Project. TMAP for short.

#### Atypicals take off

In Florida's Medicaid fee-for-service program, prescriptions of atypical antipsychotics soared during the early 1990s, while the use of older, typical antipsychotics dropped. In 2006, the average cost per prescription for the new drugs was \$221, compared with \$29 for the older drugs.

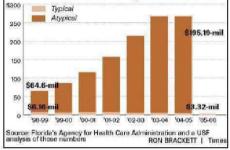
#### Count of filled prescriptions, in thousands



#### And taxpayers foot the bill

In the last five years, Florida taxpayers have spent more than \$1.1-billion on atypical antipsychotics through Medicaid. In 2005, Medicaid spent \$5.4-billion nationally on atypicals, more than it spent on any other class of drugs, including antibiotics, AIDS drugs or medications to treat high blood pressure.

Total cost of medication in Florida, in millions of dollars



**Related Links** 

a Conflicts of interest?





The goal was to bring together some of the best minds in the field to reach consensus on how best to treat schizophrenia and bipolar disorder. TMAP would tell Texas doctors: Start with this drug, and if it doesn't work, try this one. If a drug made the top of the list, the manufacturer stood to make millions.

The atypical drug companies stacked the deck: TMAP was seeded with a \$1.6-million grant from the charitable arm of the company that owns Jannsen, which makes Risperdal. The panel was packed with doctors and academics who were paid on the side from the companies that make atypicals.

Proponents of guideline committees say they discourage unproven practices, such as prescribing combinations of several antipsychotics.

Spearheading TMAP was Steven Shon, the Texas Health Department's medical director for behavioral health. A state employee, he was not allowed to accept money from the pharmaceutical companies.

He resigned amid an investigation that revealed he was taking money from Janssen. By then, with Shon's help, the Texas guidelines model had been exported to more than a dozen states, including Florida.

The Florida Behavioral Health Collaborative was the brainchild of Eli Lilly and Co., which proposed it in 2004 and, with other drug companies, gave the state \$10-million to create it.

According to Lilly spokeswoman Janice Chavers, the goal was not to help the company's profit margin, it was to give patients the best care: "Patients always must be the top priority. It can't always be about the bottom line."

The Florida collaborative convened an expert panel to recommend state standards for treating mental illness. National scholars were invited — all with financial ties to drug companies.

To treat schizophrenia, the panel decided, doctors should try an atypical first. If that didn't work, they should try a different atypical. If that still didn't work, they should try a third atypical or, if they would rather, one of the older generation drugs.

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Running Allen Jones out of his job only spurred him on. He tracked the medications guidelines in Pennsylvania — Penn-MAP — back to its birthplace in Texas.

In 2004, he filed a whistle-blower lawsuit in Texas against Johnson & Johnson, parent company of Janssen. He said that to boost sales of Risperdal, Janssen misled Texas health officials, overstating the drug's effectiveness and underplaying the risks.

"They got expert opinion to be the deciding factor," Jones said in an interview. "Essentially, the drug companies could pay people to say what the drug companies could not claim themselves," namely that they were superior to the older generation of antipsychotics.

"It was a concentrated, deliberate attempt to substitute illusion for science."

A company spokesman denied it. "Janssen has always been committed to the highest ethical standards and responsible behavior ... and this includes clear, FDA-approved information about the product's efficacy and safety profile."

Jones was not a lone wolf. The Texas attorney general joined his lawsuit in 2006 and demanded the return of tens of millions of taxpayer dollars.

The still-pending lawsuit has reverberated around the country. Nine states sued Eli Lilly, four sued Janssen, two sued AstraZeneca. Dozens more states have teamed in a joint investigation, seeking billions of dollars in restitution for money they say they overpaid for atypicals through Medicaid.

Jones, the single dad just looking for a steady job, has morphed into a full-time megathorn in the side of pharmaceutical companies. He does investigative work for law firms making cases against drug companies. Senators and congressmen call him to talk about big pharma influence.

And Pennsylvania's chief pharmacist, the man Jones was fired for speaking out about? He was indicted. The charges say that as head of Pennsylvania's mental health guidelines committee, the pharmacist took money and other perks from Pfizer and Jannsen, drug companies that make atypicals.

Looking back now, Jones is astonished by how few people it took — academics, psychiatrists, state officials — for the drug companies to influence state guidelines and bump up their sales by billions of dollars.

"The marketing was complex, but not complicated," he said. "Divert attention from the science. Divert attention to the scientists who are in your pocket."

. . .

For years, the studies paid for by the drug companies concluded that atypical antipsychotics are more effective and safer than the older class. But when governments conducted independent studies, the findings were altogether different.

In 2005, the U.S. government funded a \$60-million study called CATIE, short for Clinical Antipsychotic Trials of Intervention Effectiveness. It tracked a big sample (nearly 1,500 schizophrenics) for a long time (18 months).

CATIE analyzed the performance of all the atypicals and one of the typicals, perphenazine.

The two key conclusions: First, the atypicals generally were no more effective than the older drug. Second, slightly fewer people on atypicals dropped out of the study due to tremors, but the new drugs had their own troubling side effects, chiefly weight gain and diabetes.

What CATIE documented also was showing up in courthouses across the country: Tens of thousands of people sued Eli Lilly and AstraZeneca, saying that their drugs, Zyprexa and Seroquel, gave them diabetes and elevated blood sugar levels. Eli Lilly reports having paid \$1.2-billion to settle nearly 30,000 lawsuits.

In October 2006, a British government-funded study mirrored the CATIE findings. Its results, the study said, "refute the hypothesis that the use of (atypicals) is superior to the use of (typicals) in terms of quality of life at one year."

How to jibe these independent, government findings against the earlier studies that said atypicals were safer and more effective?

In a written commentary, the CATIE study's lead author said "the claims of superiority for the (atypicals) were greatly exaggerated.

"This may have been encouraged by an overly expectant community of clinicians and patients eager to believe in the power of new medications," wrote Dr. Jeffrey Lieberman. "At the same time, the aggressive marketing of these drugs may have contributed to this enhanced perception of their effectiveness in the absence of empirical evidence."

The marketing has been a rousing success: Of the prescribed antipsychotics in Florida last year, 86 percent were atypicals. Nationally, atypical sales have risen every year, nearly double since 2000.

Dr. Robert Rosenheck, a Yale professor who participated in the CATIE study, said the science doesn't justify that.

"There was never any evidence that warranted the amount of money we spend on atypicals," he said. "If you look at it independently, it is very clear the results say there is no benefit" to atypicals over typicals.

Yet the pharmaceutical companies get states to make them the drugs of choice, he said.

"They leverage every single angle they can to persuade every person to secure the opinion that their products are superior," Rosenheck said. "Every possible source of opinion, they use money to establish a relationship with them.

"The issue is not, 'Were these people influenced?' There is nobody who is not influenced."

In Minnesota, one of the few states with a law that requires disclosure of pharmaceutical company payments to doctors, one report showed that more than one-third of the state's psychiatrists took money from drugmakers.

Last year, a nonprofit group funded by 13 states analyzed the academic studies on atypicals. The Drug Effectiveness Review Project found that an alarming number of study authors were employed by pharmaceutical companies.

While academics and doctors often bristle at the suggestion their opinions could be influenced by pharmaceutical money, another study confirmed a not-unexpected conclusion: In trials of antipsychotic medications, the outcome usually favored the drug of the company that paid for the study.

Rosenheck believes that CATIE and other new studies are starting to shift the tide in academia - slowly.

"Obviously, there's a certain amount of resistance to admitting, one, I was wrong, and two, I was misled by companies who paid me a lot of money. That's a hard thing for a scientist to acknowledge."

He says states should change their medication guidelines so that the older class of drugs are used, unless there is a clear reason to use the newer ones. For many patients newer may be better, he says, but to continue the rampant use of atypicals despite the study findings is bad science.

"The idea that we could spend \$60-million on a study and pay no attention to it, it's like, let's

not pay attention to science and just go with marketing."

• • •

The landscape had changed in the two years since the Florida Behavioral Health Collaborative set treatment guidelines favoring atypicals.

The CATIE study had been published. Tens of thousands of patients had sued drug companies that made atypicals. The academic community was more divided about what was best.

Last July, the collaborative convened another group of experts to revisit whether Florida should rely so heavily on atypicals. Two dozen mental health professionals met at the Renaissance Hotel at Tampa's International Plaza.

They gathered in the Kalamata Room, done up in the milquetoast style of a classic hotel meeting room: long tables arranged in a square, at each seat a glass of water and a name tag.

The bland setting belied the grand stakes: The vote could swing hundreds of millions of dollars in pharmaceutical company profits. Cost to taxpayers, however, had no place in the conversation.

The meeting's two main hosts were Rajiv Tandon, chief of psychiatry for the state Department of Children and Families, and Robert Constantine, head of the Florida Behavioral Health Collaborative.

Both believe in atypicals. In two papers they co-wrote in late 2006 and early 2007, they said the CATIE study missed the point: The goal is to create a good antipsychotic effect without the tremors, making atypicals the better choice.

Constantine, a research associate professor at USF's mental health institute, is partly paid through a grant from Bristol-Myers Squibb, which markets the atypical Abilify.

Tandon, a state employee, is not allowed to accept money from drug companies. But three years ago, before coming to Florida from the University of Michigan, he was a paid consultant and on the speaker's bureau for several drug companies that make atypicals.

It was Tandon who invited the four national experts to be voting members on the Florida panel. All are consultants, serve on speakers bureaus or get research support from the drug companies that profit from atypicals.

• William Glazer, who was brought in as the schizophrenia expert, is president of Glazer Medical Solutions, a national consortium of mental health care consultants. He is a consultant to Eli Lilly and AstraZeneca.

His company Web site makes clear his bias: "Are you interested in building a case for the value of new atypical antipsychotic medications? This section offers a step-wise approach to help providers, family members, consumers and others advocate for access to these agents."

• Madhukar Trivedi, a professor of psychiatry at the University of Texas Southwestern Medical Center, is a consultant, serves on speakers bureaus or receives research money from 24 pharmaceutical companies, including all the atypical makers.

• Terence Ketter, a professor of psychiatry and behavioral sciences and chief of the bipolar clinic at Stanford University, is a paid consultant or a lecturer for all the drug companies that make atypicals.

 John Greden, chairman of the psychiatry department at the University of Michigan Medical Center, serves on scientific advisory boards for five pharmaceutical companies, including two that make atypicals.

Tandon said he selected experts who are knowledgeable, respected leaders in their field, with a working knowledge of the medication guidelines process. Because most experts have ties to the pharmaceutical companies, Tandon said, conflicts of interest are inevitable.

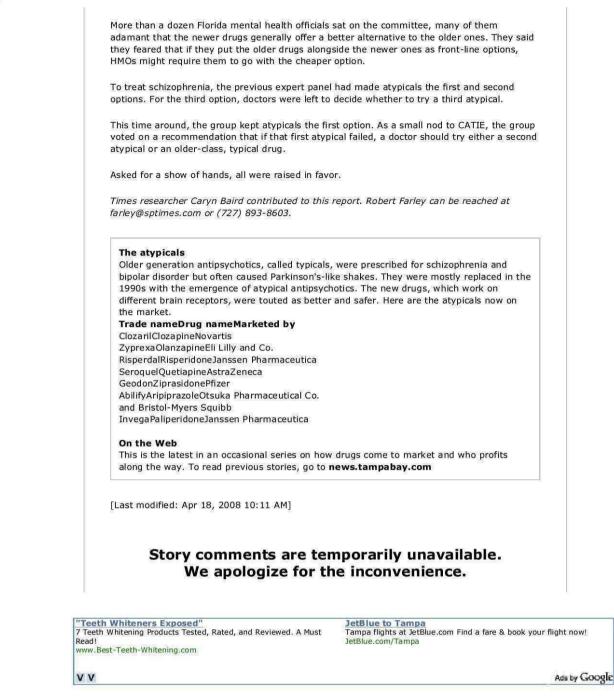
"There are clear conflicts of interest," he said. "Everyone is biased. For someone to say, 'I'm not biased,' they are not truthful or they are not introspective."

Given that there is a divide in the academic world about atypicals, why not bring in someone from the other camp, maybe somebody from the CATIE study, someone who would challenge the existing medications model?

"You could go with extremes," Tandon said. "I didn't think that was the way to go," because the point of the process is to reach a consensus.

Atypicals are usually better, he said. "Were the benefits of atypical medications exaggerated? Absolutely. And was it the pharmaceutical companies doing that? Absolutely."

Still ... "By no means are the newer medications astoundingly better, but they are better. If I have a child, I'm not going to start them on a typical."



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#### BEFORE THE STATE OF FLORIDA COMMISSION ON ETHICS

## DATE FILED

IJUN 11 2008

#### **COMMISSION ON ETHICS**

In re RAJIV TANDON,

Respondent.

Complaint No. 08-055

#### PUBLIC REPORT AND ORDER DISMISSING COMPLAINT

On Friday, June 6, 2008, the Commission on Ethics met in executive session and considered this complaint for legal sufficiency pursuant to Commission Rule 34-5.002, F.A.C. The Commission's review was limited to questions of jurisdiction of the Commission and of the adequacy of the details of the complaint to allege a violation of the Code of Ethics for Public Officers and Employees. No factual investigation preceded the review, and therefore the Commission's conclusions do not reflect on the accuracy of the allegations of the complaint.

The Commission voted to dismiss the complaint for legal insufficiency, based on the following analysis:

 This complaint and amended complaint were filed by Josefina Perez of Florida City, Florida.

 The Respondent, Rajiv Tandon, allegedly serves as the Chief of Psychiatry for the Florida Department of Children and Families.

which presumably sets guidelines on the type of drugs to be used in the treatment of mental

health disorders. According to the complaint, the Respondent misused his position by selecting panel members who favored "higher priced atypical antipsychotics" over generic drugs, and did so for the purpose of securing "a special benefit for specific atypical pharmaceutical companies who have employed him in the past."

Section 112.313(6), Florida Statutes, states:

4.

No public officer, employee of an agency, or local government attorney shall corruptly use or attempt to use his or her official position or any property or resource which may be within his or her trust, or perform his or her official duties, to secure a special privilege, benefit, or exemption for himself, herself, or others. This section shall not be construed to conflict with s. 104.31.

Pursuant to Section 112.312(9), "corruptly" is defined as

done with a wrongful intent and for the purpose of obtaining, or compensating or receiving compensation for, any benefit resulting from some act or omission of a public servant which is inconsistent with the proper performance of his or her public duties.

5. Section 112.313(6) prohibits the corrupt use of position or the resources of office for personal gain, or to benefit another. The complaint fails to indicate a possible violation of Section 112.313(6), because it fails to allege, other than in a purely conclusory fashion, any facts indicating corrupt intent. The complaint does not allege that the Respondent stands to gain by the actions of the panel, or that he is still employed by or has any other relationship with companies who will allegedly benefit. That the Respondent was employed by such companies prior to his public employment is not sufficient by itself to indicate the element of corrupt intent required by the statute. Under <u>Blackburn v. State Commission on Ethics</u>, 589 So. 2d 431 (Fla. 1<sup>st</sup> DCA 1991), the statute requires that the official acted with "wrongful intent," that is, "that she acted with reasonable notice that her conduct was inconsistent with the proper performance of her public duties and would be a violation of the law or the code of ethics in part III of chapter 112." <u>Blackburn</u>, id, at p. 434. The allegation is therefore legally insufficient to allege a violation of Section 112.313(6), Florida Statutes.

Accordingly, this complaint is hereby dismissed for failure to constitute a legally sufficient complaint with the issuance of this public report.

ORDERED by the State of Florida Commission on Ethics meeting in executive session on June 6, 2008.

2008 Rendered

Chair, Floridu Commission on Ethics

cc: Mr. Rajiv Tandon, Respondent Ms. Josefina Perez, Complainant

APM/vad