

April 27, 2010

Novartis AG  
Lichtstrasse 35  
Basel, Switzerland CH-4002  
ATTN: Public Relations or Press Office

Dear Sir or Madam:

The Project On Government Oversight (POGO) has updated its Federal Contractor Misconduct Database (<http://www.contractormisconduct.org/>), a compilation of information from public resources regarding government contractors, including Novartis AG. I have enclosed the findings relevant to your company, and I am seeking verification of this data.

Any response would be greatly appreciated, as the accuracy of this information is in the best interest of all parties. Out of fairness to Novartis AG, please be assured that any response received by POGO will be posted on the website along with the data. Please note that the database includes pending instances, but these are kept separate from resolved instances and are not included in the totals.

If you have any questions, I can be reached at (202) 347-1122. Thank you for your time and consideration.

Sincerely,

Neil Gordon  
Investigator

Enclosure

## **Instances**

### **1. Conrad v. Eon Labs (False Claims)**

**Date:** 02/22/2010 (Date of Announcement)

**Misconduct Type:** Government Contract Fraud

**Enforcement Agency:** Health and Human Servs.

**Contracting Party:** Health and Human Servs.

**Court Type:** Civil

**Amount:** \$3,500,000

**Disposition:** Settlement

**Synopsis:** Novartis subsidiary Eon Labs Inc. agreed to pay the United States \$3.5 million to resolve False Claims Act allegations relating to the company's drug Nitroglycerin Sustained Release (SR) capsules. In 1999, the Food and Drug Administration (FDA) determined that Nitroglycerin SR lacked substantial evidence of effectiveness and published a notice proposing to withdraw its approval of the product. The government claimed that, after the FDA notice, Nitroglycerin SR no longer was legally eligible for reimbursement by government health care programs, but Eon continued to submit false quarterly reports to the government that misrepresented Nitroglycerin SR's regulatory status and failed to advise that Nitroglycerin SR no longer qualified for Medicaid coverage.

### **2. Off-Label Promotion of Trileptal**

**Date:** 01/26/2010 (Date of Announcement)

**Misconduct Type:** Health

**Enforcement Agency:** Health and Human Servs.

**Contracting Party:** None

**Court Type:** Criminal

**Amount:** \$185,000,000

**Disposition:** Pleaded Guilty

**Synopsis:** Novartis Pharmaceuticals Corporation (NPC) pleaded guilty to a misdemeanor violation of the Federal Food, Drug and Cosmetic Act and agreed to pay a \$185 million fine related to the company's off-label promotion of the epilepsy drug Trileptal. Novartis is also negotiating with federal prosecutors to resolve civil claims relating to Trileptal.

### **3. Breeden v. Novartis (FMLA Retaliation)**

**Date:** 03/08/2010 (Date of Verdict)

**Misconduct Type:** Labor

**Enforcement Agency:** Non-Governmental

**Contracting Party:** None

**Court Type:** Civil

**Amount:** \$579,338

**Disposition:** Judgment Against Defendant

**Synopsis:** A federal court ruled against Novartis Pharmaceuticals Corp. and in favor of employee Mary Kate Breeden on her claim of retaliation under the Family and Medical Leave Act (FMLA) and awarded her almost \$300,000 in damages (automatically doubled under the FMLA). Breeden, who worked as a pharmaceutical sales representative for Novartis, claimed that after she told the company she was pregnant, Novartis gave her fewer and smaller accounts, and that when she returned from maternity leave her position was eliminated.

**4. Overcharging Dept. of Veterans Affairs**

**Date:** 03/11/1999 (Date of Announcement)

**Misconduct Type:** Government Contract Fraud

**Enforcement Agency:** Veterans Affairs

**Contracting Party:** Veterans Affairs

**Court Type:** Civil

**Amount:** \$8,000,000

**Disposition:** Settlement

**Synopsis:** Novartis Pharmaceuticals paid \$8 million to settle claims that its predecessor company, Ciba-Geigy, overcharged the Department of Veterans Affairs (VA). The government alleged that Ciba-Geigy failed to provide accurate pricing information to VA contract negotiators on four contracts awarded between 1987 and 1991.