

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)
)
)
v.)
)
ANNE BUTKOVITZ)
)
Defendant.)
_____)

05 CR 10128 DPW

CRIMINAL NO.

VIOLATION:

18 U.S.C. §1001 (false statements)

INFORMATION

The United States Attorney Charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

1. The defendant **ANNE BUTKOVITZ** was a resident of Newton, Massachusetts, and employed at a pediatric medical practice in Newton, Massachusetts.

Background

2. The defendant **ANNE BUTKOVITZ** was hired by a pediatric medical practice in Newton, Massachusetts (referred to in this Information as the "Pediatric Practice") in or about April 2001 as the practice manager.

3. In or about May 2001, the defendant **ANNE BUTKOVITZ** obtained the clinical study coordinator position at the Pediatric Practice.

4. In or about May 2001, the defendant **ANNE BUTKOVITZ** became the clinical study

coordinator on a trial sponsored by a world-wide publicly traded pharmaceutical company (referred to in this Information as the “Pharmaceutical Company”) called “Safety and Efficacy of Pentavalent (G1, G2, G3 G4 and P1) or Human-Bovine Reassortant Rotavirus Vaccine in Healthy Infants” (referred to in this Information as the “Clinical Study”). The objective of the study was to evaluate the efficacy and safety of a rotavirus vaccine against rotavirus disease.

5. As clinical study coordinator, the defendant **ANNE BUTKOVITZ** was responsible for organizing and conducting the study, including receiving the vaccine and placebo from the Pharmaceutical Company, maintaining study documentation and making all follow-up contacts with the study subjects as required by the Clinical Study protocol.

6. The Clinical Study was conducted under an approved United States Food and Drug Administration (“FDA”) Investigational New Drug approval. Pursuant to this approval, the FDA was authorized to review and inspect all records generated by the Clinical Study, and the FDA did indeed inspect those records at the Pediatric Practice site, and thereafter cited the Pediatric Practice for numerous violations including failing to provide the Clinical Study subjects with the required safety contacts.

7. The Clinical Study was designed to test for efficacy in approximately 3,600 subjects and safety in approximately 56,400 subjects at various sites around the world. The safety site objective was to check for cases of intussusception, also known as blocked bowel syndrome. A similar rotavirus vaccine marketed by another company had been found years earlier to cause intussusception.

8. The Pediatric Practice site, at which the defendant **ANNE BUTKOVITZ** was the clinical study coordinator for the Clinical Study was a safety site.

9. To evaluate safety, all study subjects, of which there were 33 at the Pediatric Practice, were, according to the Clinical Study protocol, followed for all serious adverse experiences (“SAEs”) for 42 days after each vaccine dose. Each subject in the study was to be given three vaccine or placebo doses at the approximate age of two, four and six months of age. To determine if SAEs occurred, the Pharmaceutical Company protocol required the study site to contact the subject’s parent(s) at intervals of 7, 14 and 42 days after each of the three vaccinations. At each contact, the study site was required to indicate on a Case Report Form whether contact was made and the date of contact and then the “yes” or “no” answers to the following questions:

- Was intussusception reported by a parent/guardian?
- Were any serious adverse experiences reported by the parent/guardian?
- Did the subject visit a health care facility for stomach illness such as diarrhea and/or vomiting?
- Was health care utilization information collected?

10. In fact, the defendant **ANNE BUTKOVITZ** did not make the required SAE contacts with parents/guardians of the Clinical Study.

11. However, the defendant **ANNE BUTKOVITZ** falsely stated on the Case Report Forms that she prepared during the period beginning on or about December 5, 2001 and continuing to on or about September 30, 2002, that: (1) she had made the contacts; and (2) no intussusception, serious adverse events, nor visits to health care facilities for stomach illness such as diarrhea and/or vomiting had occurred.

12. After September 30, 2002, the Pharmaceutical Company learned that the defendant **ANNE BUTKOVITZ** had not made the safety contacts required by the protocols of the Clinical Study

and on or about February 5, 2003, removed the Pediatric Practice, and the data it had generated, from the study.

COUNT ONE (18 U.S.C. §1001 FALSE STATEMENTS)

13. Paragraphs one through twelve of this Information are herein realleged and incorporated by reference.

14. On or about September 25, 2002, in the District of Massachusetts, the defendant

ANNE BUTKOVITZ

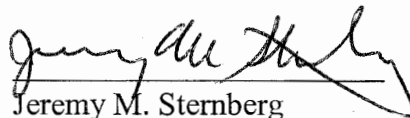
in a matter within the jurisdiction of the executive, legislative and judicial branch of the Government of the United States, knowingly and willfully made a materially false, fictitious and fraudulent statement and representation by stating that she had contacted the patient identified as 16400030 in the Clinical Study and had received negative answers to questions regarding whether that patient had suffered any serious adverse experiences.

All in violation of Title 18, United States Code, Section 1001.

Respectfully submitted,

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

By:



Jeremy M. Sternberg
Assistant U.S. Attorney

Criminal Case Cover Sheet **05 CR 10128 DPW** **U.S. District Court - District of Massachusetts**

Place of Offense: Massachusetts Category No. II Investigating Agency FDA

City Newton Related Case Information: _____

County Middlesex Superseding Ind./ Inf. _____ Case No. _____
Same Defendant _____ New Defendant _____
Magistrate Judge Case Number _____
Search Warrant Case Number _____
R 20/R 40 from District of _____

Defendant Information:

Defendant Name Anne Butkovitz Juvenile Yes No

Alias Name _____

Address 2054 Beacon Street, Newton, MA 02168

Birth date (Year only): 1958 SSN (last 4 #): 3292 Sex F Race: Caucasian Nationality: American

Defense Counsel if known: Elliott Weinstein Address: 228 Lewis Wharf
Boston, MA 02110

Bar Number: _____

U.S. Attorney Information:

AUSA Jeremy M. Sternberg Bar Number if applicable _____

Interpreter: Yes No List language and/or dialect: _____

Matter to be SEALED: Yes No

Warrant Requested Regular Process In Custody

Location Status:

Arrest Date: _____

Already in Federal Custody as _____ in _____
 Already in State Custody _____ Serving Sentence Awaiting Trial
 On Pretrial Release: Ordered by _____ on _____

Charging Document: Complaint Information Indictment

Total # of Counts: Petty _____ Misdemeanor _____ Felony 1

Continue on Page 2 for Entry of U.S.C. Citations

I hereby certify that the case numbers of any prior proceedings before a Magistrate Judge are accurately set forth above.

Date: 5-25-05 Signature of AUSA: Jeremy M. Sternberg

District Court Case Number (To be filled in by deputy clerk): _____

Name of Defendant Anne Butkovitz

	<u>Index Key/Code</u>	<u>U.S.C. Citations</u> <u>Description of Offense Charged</u>	<u>Count Numbers</u>
Set 1	<u>18 U.S.C. § 1001</u>	<u>False Statements</u>	<u>1</u>
Set 2	_____	_____	_____
Set 3	_____	_____	_____
Set 4	_____	_____	_____
Set 5	_____	_____	_____
Set 6	_____	_____	_____
Set 7	_____	_____	_____
Set 8	_____	_____	_____
Set 9	_____	_____	_____
Set 10	_____	_____	_____
Set 11	_____	_____	_____
Set 12	_____	_____	_____
Set 13	_____	_____	_____
Set 14	_____	_____	_____
Set 15	_____	_____	_____

ADDITIONAL INFORMATION: