UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
vs.	)	No. _____
	)	Violation: Title 18, United States
JOSEPH C. CALANDRA,	)	Code, Sections 1001, 1341 and 1343
MORENO L. KEPLINGER,	)	
PAUL L. WRIGHT, and	)	
JAMES B. PLANK,	)	

The SPECIAL OCTOBER 1980 GRAND JURY charges:

1. At all times material herein, Industrial Bio-Test Laboratories, Inc. (hereinafter referred to as IBT) did business in Northbrook, Illinois in the Northern District of Illinois and was a contract research laboratory which conducted animal studies on various drugs, pesticides, chemicals, and other substances, for the sponsors of said substances, in order to determine the safety and effectiveness of the substances.

2. At all times material herein, JOSEPH C. CALANDRA was President of IBT.

3. At all times material herein, MORENO L. KEPLINGER was Manager of Toxicology at IBT.

4. PAUL L. WRIGHT was Section Head for Rat Toxicology at IBT from approximately March, 1971 until September, 1972, at which time he became Manager of Toxicology for the Department of Medicine and Environmental Health at Monsanto Corporation in St. Louis, Missouri, from approximately October, 1972 until the present.

5. JAMES B. PLANK was the Senior Group Leader for Rat Toxicology at IBT until October of 1972, at which time he became the Assistant to the

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dated March 22, 1972, as part of its application for approval to test Naprosyn on humans and ultimately market the product.

8. IBT conducted two carcinogenic studies on mice (tests to determine whether a compound causes cancer) for Chemagro Corporation (Chemagro). One study was on Sencor, a herbicide, IBT Study Number 9069, and one on Nemacur, a pesticide, IBT Study Number 9068. IBT submitted the reports of the studies with a cover letter dated August 15, 1972 to Chemagro, who submitted the IBT study reports to the United States Environmental Protection Agency (EPA), the Sencor study report by mail on March 8, 1973 and the Nemacur study report by mail on October 15, 1975. Both study reports were submitted as part of Chemagro's application for approval to market these products for use on food crops.

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Manager of Toxicology at IBT from approximately October, 1972 until April, 1977.

6. IBT conducted a two-year chronic oral toxicity study on Trichlorocarbanilide (TCC) in albino rats, IBT Study Number B9575, for Monsanto Company (Monsanto). TCC is an antibacterial agent used in soaps. On or about May 10, 1976, IBT mailed its final version of the report of the study to Monsanto who submitted the IBT study report to the United States Food and Drug Administration (FDA) with a cover letter dated May 11, 1976, for that agency's use in its evaluation of the safety of TCC.

7. IBT conducted a 22 month chronic oral toxicity study on Naprosyn in albino rats, IBT Study Number B7922, for Syntex Corporation (Syntex). Naprosyn (also known as naproxen) is a drug used in the treatment of arthritis. On or about March 3, 1972, IBT mailed its report of the study to Syntex who submitted the IBT study report to FDA, with a cover letter

9. Beginning in or about 1970 and continuing until about July, 1977, in Northbrook, in the Northern District of Illinois, Eastern Division, and elsewhere,

JOSEPH C. CALANDRA,
MORENO K. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, together with co-schemers both known and unknown to the grand jury, devised and intended to devise a scheme to defraud clients and government agencies by writing and distributing false and fraudulent study reports and false and fraudulent explanations of studies and study reports, and by concealing the fraudulent nature of the study reports and explanations of studies and study reports, all by means of false and fraudulent representations and concealments, knowing and intending that the representations and concealments were false when made.

10. It was a part of the scheme to defraud that the defendants wrote and distributed false and fraudulent animal study reports to clients who commissioned the studies, which study reports were submitted by the clients to government agencies that evaluate such reports as part of their determination of the safety of those test materials.

11. It was further a part of the scheme to defraud that the defendants provided FDA with false and fraudulent written submissions which reaffirmed and made new false and fraudulent statements as to material facts, and concealments and omissions of material facts in, or pertaining to, the studies and study reports.

12. It was further a part of the scheme to defraud that the

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original version of the TOC study report was written and distributed by IBT to Monsanto on or about March 21, 1974. IBT submitted this version of the TOC report to FDA on December 12, 1976, which study report the defendants knew to be false and fraudulent in that the study report:

a. stated that the data reported were from animals that had been on the study for 24 months, when defendants then knew that the report included data from a substantial number of animals that had been on the study for significantly lesser periods of time;

b. stated that 480 animals were in the study when defendants then knew that a substantially greater number of animals were also part of the study; and

c. contained an Animal Mortality Table (Table IV) which defendants then knew to be false in that it substantially under-reported the number of animals that were in the study and the number of animals that died during the study.

13. It was further a part of the scheme to defraud that the final version of the TOC study report was written in April and May, 1976, was dated March 21, 1974, and was mailed to Monsanto by IBT on or about May 10, 1976, was submitted to FDA by Monsanto under a cover letter dated May 11, 1976, and was known by defendants to be false and fraudulent in that the study report:

a. stated that the data reported were from animals that had been on the study for 24 months, when defendants then knew that the report included data from a substantial number of animals that had been on the study for significantly lesser periods of time;

b. stated that 480 animals were in the study when defendants

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then knew that a substantially greater number of animals were also part of the study;

c. contained an Animal Mortality Table (Table IV) which defendants then knew to be false in that it substantially under-reported the number of animals that were part of the study and the number of animals that died during the study;

d. stated that 250 extra animals were on the study for 24 months and were an independent IBT "research" group, separate from the animals reported in the TCC study, when defendants then knew (1) that the so-called "research" group animals were not an independent "research" group, but were used as a source of extra animals and animal tissues for the TCC study; (2) that the so-called "research" animals had been on study for significantly lesser periods of time than 24 months; and (3) that a substantial number of the extra animals were commingled into, and reported as part of, the TCC study group;

e. stated that no histopathological examination (study of tissue characteristic of animal disease) was performed on the so-called "research" group animals, when defendants then knew that tissues from many of the so-called "research" group animals had been so examined;

f. omitted and concealed the findings listed in a table of "Histopathological Changes in Testes — Postmortem Animals", when defendants then knew that the table existed;

g. stated that postmortem autolysis (chemical deterioration of tissue after animal death) of testicular tissue precluded meaningful histopathologic evaluation of the testicular tissues of the postmortem animals, when defendants then knew that many of those tissues had been so

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examined and graded;

h. stated that the IBT pathologist, Dr. Donovan Gordon, examined the tissues of the study animals and concluded that the findings in the testes of the lowest dose level (T_1) animals were indistinguishable from the findings of the testes of the control group animals, when defendants then knew that Dr. Gordon's conclusion was that there were TCC related toxic effects in the testes of the animals in the lowest dose level; and

i. omitted and concealed, as defendants then knew, that Dr. William Ribelin, a pathologist hired by Monsanto, had examined some of the testicular tissues of the TCC study animals and had concluded that the lowest dose level showed TCC treatment-related toxic effects.

14. It was further a part of the scheme to defraud that in response to FDA questions concerning the TCC study, a written explanation of the TCC study and report, dated December 12, 1976 was prepared and submitted to FDA by IBT on December 14, 1976, which explanation defendants then knew to be false and fraudulent in that the submission:

a. stated that the data reported in the May, 1976 report (dated March 21, 1974) were from animals that had been on the study for 24 months, when defendants then knew that the report included data from a substantial number of animals that had been on the study for significantly lesser periods of time;

b. concealed, as defendants then knew, that the animal mortality in the TCC study was substantially greater than reported in any version of the study report;

c. stated that 250 extra animals were on the study for 24 months and were an independent IBT "research" group, separate from the

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animals reported in the TCC study, when defendants then knew (1) that the so-called "research" group animals were not an independent "research" group, but were used as a source of extra animals and animal tissues for the TCC study; (2) that the so-called "research" animals had been on study for significantly lesser periods of time than 24 months; and (3) that a substantial number of the extra animals were commingled into, and reported as part of, the TCC study group;

d. concealed that histopathologic examinations were performed on a substantial number of the so-called "research" animals, when defendants then knew that such examinations had been performed; and

e. omitted and concealed, as defendants then knew, that Dr. William Ribelin, a pathologist hired by Monsanto, had examined some of the testicular tissues of the TCC study animals and had concluded in a written report that the lowest dose level showed TCC treatment-related toxic effects.

15. It was further a part of the scheme to defraud that the final study report on Naprosyn, dated January 4, 1972, was written by IBT and was received through the mail by Syntex from IBT on or about March 3, 1972, and submitted to the FDA by Syntex under cover letter dated March 22, 1972, which report defendants then knew to be false and fraudulent in that the report:

a. contained individual animal and summary animal data allegedly based on blood and urine tests performed on or about the time of final sacrifice of the study, when defendants then knew that no such tests had been conducted and that the data was fabricated and false; and

b. was supplemented by an Appendix II which was submitted to FDA by Syntex on April 9, 1974 which purported to represent, among other things, all the findings from gross examination of the study animals, when

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defendants then knew that for a substantial portion of the gross findings for postmortem animals, no such examinations were performed and the findings were fabricated and false.

16. It was further a part of the scheme to defraud that in response to FDA questions raised in September, 1976 concerning the Naprosyn study, a letter signed by Joseph C. Calandra and an explanation of the Naprosyn study dated November 11, 1976 was written and submitted to FDA, and a copy was mailed to Syntex under cover letter dated November 17, 1976. Defendants then knew that the November 11, 1976 submission to the FDA was false and fraudulent in that the submission:

a. stated that the data reported for individual animal and summary animal blood and urine values allegedly collected on or about the time of final sacrifice of the study were accurate, when defendants then knew that the data were fabricated and false; and

b. stated that gross examinations were performed on the postmortem animals and that the data from those examinations reported in Appendix II were obtained from animal cage cards and animal disposition sheets, when defendants then knew that for a substantial number of the reported postmortem animal findings no gross examinations were performed and the data were fabricated and false.

17. It was further a part of the scheme to defraud that IBT prepared and mailed to Chemagro final reports for the Sencor and Nemacur studies under cover letter dated August 15, 1972 to Chemagro. Chemagro submitted the IBT Sencor study report to EPA by mail on or about March 8, 1973, and submitted the IBT Nemacur study report to EPA by mail on or about October 15, 1975, which reports defendants then knew to be false and

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fraudulent in that each report:

a. stated that all the mice on the study were fed the test material for 18 months, when defendants knew that (1) the study only ran for 14 months; and (2) the mice sacrificed and examined at the end of the study included a substantial number of mice which had been fed the test material 14 months or less;

b. contained a Mortality Table which defendants then knew substantially under-reported the number of animals that were on the study and the number of animals that died during the study;

c. concealed that a larger number of extra mice were added to and were a part of the study; and

d. stated that there was a third positive control group fed benzedine, when the defendants then knew that no such control group had been conducted with these studies.

18. It was further a part of the scheme to defraud that IBT wrote an "Addendum Report to Chemagro" regarding the Sencor study report and mailed it to Chemagro on or about December 21, 1973, which addendum Chemagro mailed to EPA on or about October 8, 1974, and which defendants knew to be false and fraudulent in that the addendum:

1. listed the number of days that each mouse was on the study as if the study had run for 18 months, when defendants then knew that the mice had been on the study for significantly lesser periods of time;

2. omitted and concealed that a substantially greater number of mice were on the study than reported; and

3. listed for the individual animals designated as PCIII, their alleged number of days on the study and gross pathological findings which

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information defendants knew was false because no such positive control group had been conducted with this study.

19. It was further a part of the scheme to defraud that an IBT audit was conducted on the Chemagro studies in April, 1976 which documented that the studies were false, as specified above in Paragraph 17a, and that the defendants concealed the results of this audit from Chemagro until July, 1977.

20. It was further a part of the scheme to defraud that the United States mails and interstate wire communications were used in furtherance of the scheme.

21. On or about May 10, 1976, in the Northern District of Illinois, Eastern Division,

JOSEPH C. CALANDRA,
MORENO L. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, for the purposes of executing the aforesaid scheme to defraud, and attempting to do so, knowingly did cause to be placed in the United States mails the final version of the TOC study report, addressed to:

Daniel Roush
Monsanto Company
800 Lindbergh Blvd.
St. Louis, Missouri

to be sent and delivered by the United States Postal Service according to the directions thereon.

In violation of Title 18, United States Code, Section 1341.

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COUNT TWO

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Twenty of Count One of the indictment are realleged herein.

2. On or about August 11, 1976, in the Northern District of Illinois, Eastern Division,

JOSEPH C. CALANDRA,
MORTON L. REPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, for the purposes of executing the aforesaid scheme to defraud, and attempting to do so, knowingly did cause to be placed in the United States mails a letter from Joseph C. Calandra dated August 11, 1976, addressed to:

Dr. Carl M. Leventhal
Deputy Director, Bureau of Drugs
Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20852

to be sent and delivered by the United States Postal Service according to the directions thereon.

In violation of Title 18, United States Code, Section 1341.

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COUNT THREE

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Twenty of Count One of this indictment are realleged herein.

2. On or about November 17, 1976, in the Northern District of Illinois, Eastern Division,

JOSEPH C. CALANDRA,
MORENO L. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, for the purposes of executing the aforesaid scheme to defraud, and attempting to do so, knowingly did cause to be placed in the United States mails a copy of the written submission by IBT to the FDA regarding Naprosyn dated November 11, 1976, addressed to:

Mr. Virgil Thompson
Syntex Corporation
3401 Hillview Avenue
Palo Alto, California 94304

to be sent and delivered by the United States Postal Service according to the directions thereon.

In violation of Title 18, United States Code, Section 1341.

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COUNT FOUR

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Twenty of Count One of this indictment are realleged herein.

2. In or about October, 1976, in the Northern District of Illinois, Eastern Division,

JOSEPH C. CALANDRA,
MORENO L. REPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, for the purposes of executing the aforesaid scheme to defraud, and attempting to do so, knowingly did transmit and cause to be transmitted in interstate commerce, by means of wire communication, certain signs, signals and sounds, to wit: a long distance telephone call between IBT and Dr. D.W. Lamb at Chemagro in Kansas City, Missouri.

In violation of Title 18, United States Code, Section 1343.

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COUNT FIVE

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Six of Count One of this indictment are realleged herein.

2. At all times material herein, the Food and Drug Administration (FDA) was an agency of the United States Government.

3. On or about May 10, 1976, in Northbrook, in the Northern District of Illinois, Eastern Division, and elsewhere,

JOSEPH C. CALANDRA,
MORENO L. REPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, wilfully and knowingly did make, and cause to be made, false, fictitious and fraudulent statements and representations as to material facts and concealed and covered up material facts, in a matter within the jurisdiction of FDA, to wit: "Report to Monsanto Company, Two-Year Chronic Oral Toxicity Study with TCC in Albino Rats, BTL 71-8, March 21, 1974, IBT No. 9575," which study report was submitted to FDA by Monsanto under cover letter dated May 11, 1976. The aforesaid false, fictitious and fraudulent statements and representations and omissions as to material facts are listed in Paragraph Thirteen of Count One of this indictment and are realleged herein.

In violation of Title 18, United States Code, Section 1001.

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COUNT SIX

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Six of Count One and Paragraph Two of Count Five of this indictment are realleged herein.

2. On or about December 12, 1976, in Northbrook, in the Northern District of Illinois, Eastern Division, and elsewhere,

JOSEPH C. CALANDRA,
MORENO L. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, wilfully and knowingly did make, and cause to be made, false, fictitious and fraudulent statements and representations as to material facts and concealed and covered up material facts, in a matter within the jurisdiction of the FDA, to wit: a written explanation to the FDA by IBT regarding IBT's "Report to Monsanto Company, Two-Year Chronic Oral Toxicity Study with TCC in Albino Rats, BTL 71-8, March 21, 1974, IBT No. 9575." The aforesaid false, fictitious and fraudulent statements and representations and omissions as to material facts are listed in Paragraph Fourteen of Count One of this indictment and are realleged herein.

In violation of Title 18, United States Code, Section 1001.

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COUNT SEVEN

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Six of Count One and Paragraph Two of Count Five of this indictment are realleged herein.

2. On or about December 12, 1976, in Northbrook, in the Northern District of Illinois, Eastern Division, and elsewhere,

JOSEPH C. CALANDRA,
MORENO L. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. PLANK,

defendants herein, wilfully and knowingly did make, and cause to be made, false, fictitious and fraudulent statements and representations as to material facts and concealed and covered up material facts, in a matter within the jurisdiction of the FDA, to wit: the original version of the study report called "Report to Monsanto Company, Two-Year Chronic Oral Toxicity Study with TCC in Albino Rats, MTL 71-8, March 21, 1974, IBT No. 9575", which was submitted along with the written explanation of the TCC study to the FDA under cover letter dated December 12, 1976 by IBT. The aforesaid false, fictitious and fraudulent statements and representations and omissions as to material facts are listed in Paragraph Twelve of Count One of this indictment and are realleged herein.

In violation of Title 18, United States Code, Section 1001.

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COUNT EIGHT

The SPECIAL OCTOBER 1980 GRAND JURY further charges:

1. Paragraphs One through Five and Paragraph Seven of Count One and Paragraph Two of Count Five of this indictment are realleged herein.

2. On or about November 11, 1976, in Northbrook, in the Northern District of Illinois, Eastern Division, and elsewhere,

JOSEPH C. CALANDRA,
MORENO L. KEPLINGER,
PAUL L. WRIGHT, and
JAMES B. FLANK,

defendants herein, wilfully and knowingly did make, and cause to be made, false, fictitious and fraudulent statements and representations as to material facts and concealed and covered up material facts, in a matter within the jurisdiction of the FDA, to wit: a letter and written explanation to the FDA prepared and submitted by IBT dated November 11, 1976 regarding the IBT study report on Naprosyn called: "Report to Syntex Research, Division of Syntex Corporation, 22-Month Chronic Oral Toxicity Study with RS 3540 Albino Rats, January 4, 1972, IBT No. B7922". The aforesaid false, fictitious and fraudulent statements and representations and omissions as to material facts are listed in Paragraph Sixteen of Count One of this indictment and are realleged herein.

In violation of Title 18, United States Code, Section 1001.

A TRUE BILL:

FOREPERSON

UNITED STATES ATTORNEY

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