

ABBOTT

Global Medical Services

Postmarketing Safety
Dept. R422, AP34-2S
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6008

Re: No adverse event

Date: September 27, 2004

Phone call received from a consumer on September 27, 2004. The patient has been taking the tradename form of LEVOTHYROXINE from Abbott Laboratories for years. In approximately July 2004, the patient was switched to generic LEVOTHYROXINE from [REDACTED]. In September 2004, the patient experienced generalized achiness. This case was discussed with Pamela Rieb. A letter will be sent to [REDACTED] regarding this adverse event.

Pamela Rieb

Post-Marketing Safety Manager

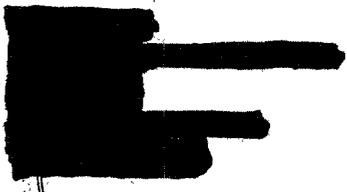
CONFIDENTIAL



Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

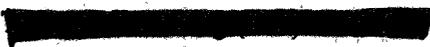
September 27, 2004



COPY

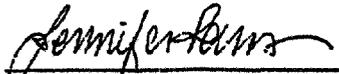
To Whom it May Concern;

Abbott Laboratories has received an adverse event report in which your product, LEVOTHYROXINE[®], was identified as a suspect drug. We are forwarding this report to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

The reporter's information is: 

Should you wish to contact us, please call 1-800-633-9110

Sincerely,


Jennifer Ramos, RN, BSN

Abbott Laboratories
Medical Services Specialist
Global Pharmaceutical and Research Department



Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

November 2, 2004

COPY

To Whom it May Concern;

Abbott Laboratories has received an adverse event report in which your product, Levothyroxine Sodium Tablet[®][™], was identified as a suspect drug. We are forwarding this information to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

Patient information:

[REDACTED]

Phone number:

[REDACTED]

The patient experienced increased fatigue and feeling cold with Levothyroxine Sodium Tablets.

Should you wish to contact us, please call 1-800-633-9110

Sincerely,

Ray Labayo, RN, BSN
Abbott Laboratories
Medical Services Specialist
Global Pharmaceutical and Research Department

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ABBOTT

Global Medical Services

Postmarketing Safety
Dept. R422, AP34-2S
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6008

No Adverse Event Memo
Re: Synthroid

Date: November 2, 2004

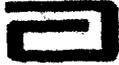
On 02 Nov 2004, we received a phone call from [REDACTED] who stated that she was experiencing adverse events with Synthroid. When the patient was contacted, the suspect medication was identified as Levothyroxine Sodium tablets which are manufactured by [REDACTED]. The patient said she was recently switched to the Levothyroxine Sodium tablets from Synthroid and was experiencing increased fatigue and feeling cold. There was no adverse event with Synthroid. No further action was required.

Ray Labayo RN, BSN *RL* 02 NOV 2004

Post-Marketing Safety Post marketing safety Analyst

Pamela Bieb
Post-Marketing Safety Manager

SER MUST VERIFY CURRENCY OF PRINTED SOP/GUIDELINE AT TIME OF IMPLEMENTATION



Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development

Medical Information and Product Safety

RECORD OF CONTACT

DATE: 11/2/04 TIME: 8:30 ^{am} _{pm}

Adverse Reaction

AEGIS Database search

Product: Synthroid

Reporter Name: [REDACTED]

Physician Pharmacist Nurse Patient Abbott Rep* Other

Reporter Address: _____
Street

City State Zip

Telephone: ([REDACTED]) [REDACTED] *Territory _____

Patient identifiers: _____ Sex _____ Age _____ Initials _____

ADVERSE EVENT(S): _____

SUMMARY OF DISCUSSION:

This individual called this AM & stated she was on Synthroid & had been switched to another levothyroxine product ([REDACTED]). Since switching she had experienced increased fatigue & feeling cold. She was instructed to contact her MD & the appropriate company to report these ADE's. I understand PMS is collecting reports of this nature, [REDACTED] on this specific product.

Front Desk Staff: [REDACTED] Signature

Date: 11/2/04



Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

Novmeber 19th, 2004



COPY

To Whom it May Concern;

Abbott Laboratories has received the adverse events of fast pulse, throat tightness, and increased appetite in which your product, LEVOTHYROXINE®™, was identified as a suspect drug. The patient experiencing the events is [REDACTED]. We are forwarding this letter to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

Should you wish to contact us, please call 1-800-633-9110

Sincerely,


Ann Compton, RN

Abbott Laboratories
Medical Services Specialist
Global Pharmaceutical and Research Department

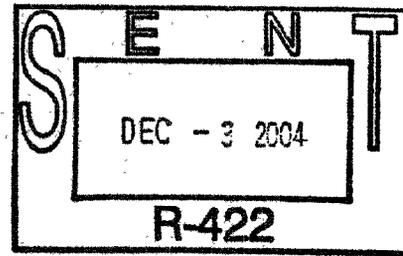
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Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

December 03, 2004



AER #:

To Whom It May Concern;

Abbott Laboratories has received an adverse event report in which your product, Generic Levothyroxine was identified as a suspect drug. We are forwarding this report to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

Should you wish to contact us, please call 1-800-633-9110

Sincerely,

Annette Larsen, RN

Abbott Laboratories
Medical Services Analyst
Global Pharmaceutical and Research Department

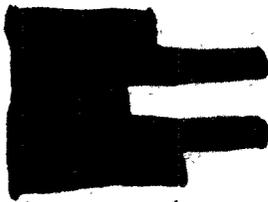
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Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

September 27, 2004



AER #: [REDACTED]

To Whom it May Concern;

Abbott Laboratories has received an adverse event report in which your product, Generic Levothyroxine was identified as a suspect drug. We are forwarding this report to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

Should you wish to contact us, please call 1-800-633-9110

Sincerely,

A handwritten signature in cursive script, appearing to read 'Anette Larsen'.

Annette Larsen, RN

Abbott Laboratories
Medical Services Analyst
Global Pharmaceutical and Research Department

MED WATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

MR report # _____
 Distributor report # _____
 FDA Use Only

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: [redacted] or Date of birth: [redacted]	3. Sex female <input checked="" type="checkbox"/> male <input type="checkbox"/>	4. Weight UNK lbs or UNK kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year) ??/??/02	4. Date of this report (month/year) 09/13/04
--	--

5. Describe event or problem

Consumer report from the USA of hair loss, excessive perspiration, depression, and menopausal-like symptoms coincident with LEVOTHYROXINE (SYNTHROID) therapy. In 1999, the patient began SYNTHROID therapy for thyroid cancer. In 2002, the patient experienced hair loss. In 2002, the dosage of SYNTHROID therapy was increased. In 2002, the patient recovered from the hair loss. In Aug 2004, the patient was switched to GENERIC LEVOTHYROXINE therapy. In Aug 2004, after the switch to GENERIC LEVOTHYROXINE therapy, the patient experienced excessive perspiration, depression, and menopausal-like symptoms. GENERIC LEVOTHYROXINE therapy was ongoing. The patient has not recovered from the excessive perspiration, depression, and menopausal-like symptoms. The reporter declined to have the physician contacted. GENERIC LEVOTHYROXINE was also considered suspect.

6. Relevant tests/laboratory data, including dates

Not reported

Continued

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

The patient quit smoking in 1989, is a nondrinker, and has no known allergies.

C. Suspect medication(s)

1. Name (give labeled strength & unit/labeled, if known)

#1 SYNTHROID 125 mcg (SYNTHROID) (LEVOTHYROXINE) (LEVOTHYROXINE)
 #2 GENERIC LEVOTHYROXINE

Continued

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 125 mcg, 1 in 1 D, Per oral	#1 ??/??/99 - ??/??/02
#2 137 mcg, 1 in 1 D, Per oral	#2 08/??/04 - Ongoing

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 THYROID CANCER	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 THYROID CANCER	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 UNKNOWN	#1 UNKNOWN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 UNKNOWN	#2 UNKNOWN	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
1) OMEPRAZOLE Unknown - Ongoing
2) FAMOTIDINE Unknown - Ongoing
3) ROFECOXIB Unknown - Ongoing
4) LISINAPRIL Unknown - Ongoing
5) ESTROGENS Unknown - Ongoing

Continued

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)	2. Phone number
PPD Pharmacovigilance 200 Abbott Park Road D-491 AP30-1E Abbott Park, Illinois 60064-6157 USA (Informing Unit)	847-937-5533
4. Date received by manufacturer (month/year) 09/13/04	3. Report source (check all that apply)
6. If IND, protocol #	<input type="checkbox"/> foreign
7. Type of report (check all that apply)	<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic	<input checked="" type="checkbox"/> consumer
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	<input type="checkbox"/> health professional
9. Mfr. report number [redacted]	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other: _____

5. (A)NDA # 21-402
IND # _____
PLA # _____
pre-1938 <input type="checkbox"/> yes
OTC product <input type="checkbox"/> yes

8. Adverse event term(s)

- Hair loss (Alopecia)
- Perspiration excessive (Hyperhidrosis)
- Depression (Depression)
- Menopausal symptoms (Menopausal symptoms)

E. Initial reporter

1. Name & address	phone #
In Confidence USA	

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	Consumer	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

B.6 Relevant tests/laboratory data, including dates (Cont...)

Lab Result :

Test name	Test date	Test result	Normal value	Classification
See Narrative Lab Results	UNK	UNK		

C. Suspect medication (Cont...)

Seq No. : 1
C.1 Suspect medication : SYNTHROID 125 mcg (SYNTHROID) (LEVOTHYROXINE)
(LEVOTHYROXINE)
C.2 Dose, frequency & route used : 2) 137 mcg, 1 in 1 D, Per oral
C.3 Therapy Dates (or duration) : 2) ??/??/02 - 08/??/04
C.5 Dechallenge
C.8 Rechallenge

Seq No. : 2
C.1 Suspect medication : GENERIC LEVOTHYROXINE

C10. Concomitant medical products

Seq No. : 1
Concomitant Medical Product : OMEPRAZOLE
Dose, frequency & route used : 1) , As required, Per oral
Diagnosis for use(indication) : 1) STOMACH

Seq No. : 2
Concomitant Medical Product : FAMOTIDINE
Dose, frequency & route used : 1) , As required, Per oral
Diagnosis for use(indication) : 1) STOMACH

Seq No. : 3
Concomitant Medical Product : ROFECOXIB
Dose, frequency & route used : 1) 1 in 1 D, Per oral
Diagnosis for use(indication) : 1) PAIN

Seq No. : 4
Concomitant Medical Product : LISINOPRIL
Diagnosis for use(indication) : 1) PREVENTION OF HEART DISEASE

Seq No. : 5
Concomitant Medical Product : ESTROGENS CONJUGATED
Dose, frequency & route used : 1) 0.625 mg, 1 in 1 D, Per oral
Therapy Dates : 1) ??/??/94 - 04/??/04
Diagnosis for use(indication) : 1) UNKNOWN INDICATION



**Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development**

ADVERSE EVENT REPORTING FORM

This case requires expedited processing for local requirements.

Sender Information

Name of Sender: [REDACTED]

Affiliate Location: [REDACTED]

Country Where Adverse Event Occurred: [REDACTED]

Sender Phone:

Sender Fax Number:

Affiliate Cross-Reference/AER Number: [REDACTED]

Sender Comments:

Suspect Abbott Product: *Synthroid*

Product Owner (use Product Owner List for reference):
 PPD-PMS PPD-IND AI HPD Ross

Report Source (for reference):

- Spontaneous
- Academic
- PMS Studies
- Named Patient Program
- Affiliate Expanded Access
- Clinical
- Abbott Clinical Trials (Phases I-IV)
- AI Expanded Access
- Literature

Receiver Information (Please fax report to the appropriate Division)

Division	Report Source	Fax #
PPD PMS Pharmaceutical Products	Spontaneous Reports Only	(847) 935-7931
PPD IND Pharmaceutical Products	Clinical Reports Only	(847) 938-0660
AI / Ross Nutritionals / Ross Over-the-Counter	Spontaneous Reports Only	(847) 935-7931
AI / Ross Nutritionals / Ross Over-the-Counter	Clinical Reports Only	(847) 938-0660
HPD Pharmaceutical Products	All Reports	(847) 936-0126
Ross Pharmaceutical Products	All Reports	(614) 624-3499

Report Information

Report Type: Serious Nonserious

Please check one of the following: Initial Follow-Up

Number of Pages (including cover): _____ Date: 9/13/04



**Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development**

ADVERSE EVENT REPORTING FORM

Affiliate Tracking #: [REDACTED]

AER #: [REDACTED]

Affiliate/Location: [REDACTED]

<input checked="" type="checkbox"/> Initial Abbott Awareness Date: <u>9/13/04</u>	<input type="checkbox"/> Follow-Up Abbott Awareness Date: _____
Initial Report Received via (check all that apply): <input checked="" type="checkbox"/> Phone <input type="checkbox"/> Written <input type="checkbox"/> Fax <input type="checkbox"/> Electronic	<input type="checkbox"/> Follow-Up Report #: _____ <input type="checkbox"/> New Information Only

Report Source (check all that apply):

<input type="checkbox"/> Comarketer	<input checked="" type="checkbox"/> Consumer/Patient	<input type="checkbox"/> Physician
<input type="checkbox"/> Healthcare Professional	<input type="checkbox"/> Health Authority	<input type="checkbox"/> Other _____
<input type="checkbox"/> Literature	<input type="checkbox"/> Company Representative	

Studies (Check one)

<input type="checkbox"/> Academic	<input type="checkbox"/> Named Patient Program	<input type="checkbox"/> Expanded Access	<input type="checkbox"/> Other: _____
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If report is a study, please complete: Title of Study _____ Patient # _____ Investigator # _____ Protocol # _____ Study/type of drug being taken at time event occurred: <input type="checkbox"/> Lead-in <input type="checkbox"/> Abbott Drug <input type="checkbox"/> Placebo <input type="checkbox"/> Blinded <input type="checkbox"/> Comparator _____	Was patient in a prior study? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Prior Patient # _____ Prior Protocol # _____ Prior study/type of drug: <input type="checkbox"/> Drug _____ <input type="checkbox"/> Placebo <input type="checkbox"/> Blinded <input type="checkbox"/> Comparator _____ Start Date of Drug _____ Stop Date of Drug _____
--	--

Reporter Information

Customer #: _____

Initial Reporter/ Title/Pharmacist Name
[REDACTED]

Occupation/Specialty: _____

Institution/Pharmacy Name
[REDACTED]

Address:
[REDACTED]

Primary Reporter?

Phone: [REDACTED]
FAX: _____
E-Mail: _____

Prescriber? Yes No Unknown Not Reported
Do Not Report Name Relative _____

Customer #: _____

Additional Reporter /Title/Pharmacist Name
MD contact declined

Occupation/Specialty: _____

Institution/Pharmacy Name _____

Address: _____

Primary Reporter?

Phone: _____
FAX: _____
E-Mail: _____

Prescriber? Yes No Unknown Not Reported
Do Not Report Name Relative _____



ADVERSE EVENT REPORTING FORM

Affiliate Tracking # [REDACTED]

AER # [REDACTED]

* Abbott also considers these events as serious.

Adverse Event		Seriousness Criteria	Reporter Opinion of Causality	Event Resolution
Adverse Event <i>hair loss</i>		<input type="checkbox"/> Death Date: <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged Hospitalization <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Medically Important Event <input type="checkbox"/> Elective Abortion* <input type="checkbox"/> Miscarriage*	<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Probably Not <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Alternative Etiology, if Applicable	<input checked="" type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovered/Resolved With Sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported
Onset Date/Time	End Date/Time			
Time to Onset	Duration			
Adverse Event <i>EXCESSIVE perspiration</i>		<input type="checkbox"/> Death Date: <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged Hospitalization <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Medically Important Event <input type="checkbox"/> Elective Abortion* <input type="checkbox"/> Miscarriage*	<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Probably Not <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Alternative Etiology, if Applicable	<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input checked="" type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovered/Resolved With Sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported
Onset Date/Time	End Date/Time			
Time to Onset	Duration			
Adverse Event <i>depression</i>		<input type="checkbox"/> Death Date: <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged Hospitalization <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Medically Important Event <input type="checkbox"/> Elective Abortion* <input type="checkbox"/> Miscarriage*	<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Probably Not <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Alternative Etiology, if Applicable	<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input checked="" type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovered/Resolved With Sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported
Onset Date/Time	End Date/Time			
Time to Onset	Duration			
Adverse Event <i>menopausal-like symptoms</i>		<input type="checkbox"/> Death Date: <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged Hospitalization <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Medically Important Event <input type="checkbox"/> Elective Abortion* <input type="checkbox"/> Miscarriage*	<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Probably Not <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Alternative Etiology, if Applicable	<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input checked="" type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovered/Resolved With Sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported
Onset Date/Time	End Date/Time			
Time to Onset	Duration			
Adverse Event		<input type="checkbox"/> Death Date: <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged Hospitalization <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Medically Important Event <input type="checkbox"/> Elective Abortion* <input type="checkbox"/> Miscarriage*	<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Probably Not <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported Alternative Etiology, if Applicable	<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovered/Resolved With Sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported
Onset Date/Time	End Date/Time			
Time to Onset	Duration			



Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development

ADVERSE EVENT REPORTING FORM

Affiliate Tracking # _____

AER # _____

Abbott Suspect Product(s)

Product Name	Action Taken*	NDC #	Total Daily Dose	Unit Dose & Frequency	Dates/Times of Administration			Indication(s)
					Route	Start/Duration**	End**	
Abbott Primary Product: <u>Synthroid</u> Lot # <u>Juk</u> Exp. Date(s) <u>Juk</u> <input type="checkbox"/> On query, reporter declined to provide Lot # information. <input type="checkbox"/> Other: _____	<input type="checkbox"/> Ong <input type="checkbox"/> Chg <input type="checkbox"/> None <input checked="" type="checkbox"/> Disc. <input type="checkbox"/> Unk <input type="checkbox"/> NR	<u>Juk</u>	<u>125ug</u> <u>137ug</u>	<u>QD</u> <u>QD</u>	<u>PO</u> <u>PO</u>	<u>1999</u> <u>2002</u>	<u>2002</u> <u>8/01</u>	<u>thyroid</u> <u>cancer</u>
Abbott Product: _____ Lot # _____ Exp. Date(s) _____ <input type="checkbox"/> On query, reporter declined to provide Lot # information. <input type="checkbox"/> Other: _____	<input type="checkbox"/> Ong <input type="checkbox"/> Chg <input type="checkbox"/> None <input type="checkbox"/> Disc. <input type="checkbox"/> Unk <input type="checkbox"/> NR							
Abbott Product: _____ Lot # _____ Exp. Date(s) _____ <input type="checkbox"/> On query, reporter declined to provide Lot # information. <input type="checkbox"/> Other: _____	<input type="checkbox"/> Ong <input type="checkbox"/> Chg <input type="checkbox"/> None <input type="checkbox"/> Disc. <input type="checkbox"/> Unk <input type="checkbox"/> NR							

* Action Taken Key: Ong = Ongoing Chg = Dose change Disc = Discontinued Unk = Unknown NR = Not Reported

** Start and End Code Key: Ong = Ongoing administration Unk = Unknown NR = Not Reported

If suspect drug discontinued, did event(s) abate? Yes Improved Resolved No Unknown Not Reported

If improved or resolved, which event(s)? _____

If suspect product reintroduced, did event(s) reappear? Yes No Unknown Not Reported

If yes, which event(s)? _____

Product Complaint Information

Comments: _____

Sample Requested Pharmacy Replacement Requested (Note which location the product was distributed for replacement)

Additional Information

Batch Record Review Requested Assay Requested



ADVERSE EVENT REPORTING FORM

Affiliate Tracking # [REDACTED]

AER # [REDACTED]

Event Description

Consumer report for the onset of hair loss, excessive perspiration, depression, and menopausal like symptoms c/w (Synthroid) Levothyroxine therapy. In 1999, the pt began Synthroid therapy for thyroid cancer. In 2000, the pt experienced hair loss. In 2001, Synthroid was increased. In 2002, the pt recovered from the hair loss. In Aug 2004, the pt was switched to Generic Levothyroxine therapy. In Aug 2004 after the switch to generic, the pt experienced excessive perspiration, depression, and menopausal like symptoms. Generic Levothyroxine therapy was ongoing. The pt has not recovered from the excessive perspiration, depression, and menopausal like symptoms. The reporter declined to have the physician contacted. Generic Levothyroxine was also considered suspect.

Signature and Date:

Signature: [REDACTED]

Date: 9/13/04

ABBOTT

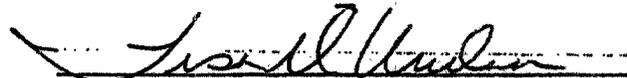
Global Medical Services

Postmarketing Safety
Dept. R422, AP34-2S
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6008

No Adverse Event Memo
Re: Synthroid
AAD: 19 Apr 2005

Date: 22 Apr 2005

On 19 Apr 2005, a phone call was received from a consumer's relative regarding LEVOTHYROXINE SODIUM ([REDACTED]). After speaking with [REDACTED] during a follow-up phone call made on 21 Apr 2005, there was not an adverse event that occurred with an Abbott Labs product. The consumer's relative was switched from an Abbott Labs SYNTHROID product to a LEVOTHYROXINE SODIUM product manufactured by [REDACTED] in Jan 2005. In Feb 2005, the consumer experienced an adverse event coincident with the LEVOTHYROXINE SODIUM product manufactured by [REDACTED]. On 21 Apr 2005, a letter to [REDACTED] informing them of the adverse event was sent.



Lisa M. Unda R.N.
Medical Safety Analyst



Post-Marketing Safety Manager

CONFIDENTIAL



Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

April 21, 2005

[REDACTED]

To Whom it May Concern;

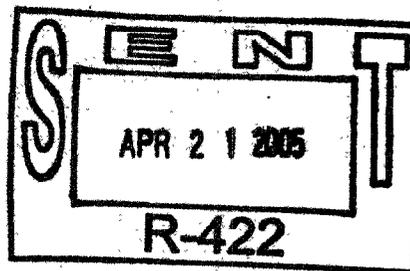
Abbott Laboratories has received an adverse event report in which your product, LEVOTHYROXINE SODIUM[®], was identified as a suspect drug. The reporter was a relative of the consumer whose name is [REDACTED]. The reporter can be contacted by telephone or mail. The telephone number [REDACTED]. The address [REDACTED]. The consumer is a [REDACTED] with a history of obsessive-compulsive behavior, schizophrenia, and increased blood pressure. The consumer began LEVOTHYROXINE SODIUM 200 mcg daily in Jan 2005. The relative called to report an adverse event of increased obsessive-compulsive behavior since Feb 2005. I am forwarding this information by our company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

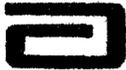
Should you wish to contact us, please call 1-800-633-9110

Sincerely,

Lisa M. Unda R.N. B.S.N.

Abbott Laboratories
Medical Services Analyst
Global Pharmaceutical and Research Department





Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development

RECORD OF CONTACT

DATE: 4/19/05 TIME: 2:14 ^{am}_{pm}

Adverse Event

AEGIS Database search

Product: Synthroid / [REDACTED]

Reporter Name: [REDACTED]

Physician Pharmacist Nurse Patient Abbott Rep* Other MOTHER

Reporter Address: [REDACTED]
Street: [REDACTED]
City: [REDACTED] State: [REDACTED] Zip: [REDACTED]

Telephone: [REDACTED] *Territory: [REDACTED]

Patient identifiers: [REDACTED] Sex: [REDACTED] Age: [REDACTED] Initials: [REDACTED]

ADVERSE EVENT(S): increased obsessive/compulsive behavior

SUMMARY OF DISCUSSION:

Has a 41yr-old daughter who was on Synthroid for many, many years. Is also taking Zoloft & Navane. In January of 2005 [REDACTED] State payments would not allow for Synthroid to be dispensed. Was switched to [REDACTED] the [REDACTED] brand 200mg. The mother is noticing changes in her behavior. Is becoming more obsessive in her behavior. Did not experience any changes in behavior when on Synthroid. Mother is agreeable to follow-up from PMS. Contact me if you have any questions. Is not suicidal.

Name: [REDACTED] Signature

Date: 4/19/05