

Para: Profesor Ken Woods
Ejecutivo Principal
Agencia Reguladora de Productos de
Medicina y Salud (MHRA, por sus siglas
en inglés)

Copia: A todas las Agencias de Salud
de Europa (miembros de los Estados
involucrados con Strattera)

15 de mayo del 2008.

Strattera: Eli Lilly dio información falsa acerca de las muertes provocadas por el "tratamiento" con Strattera – solicitud imperativa para iniciar una investigación completa

En abril le entregué información a la MHRA acerca de casos de muertes reportados en conexión con el tratamiento de Strattera. La agencia no ha contestado aún y no se ha informado de ninguna investigación que se haya llevado a cabo sobre los casos fatales que se reportaron.

El reporte actualizado a continuación, **una compilación de casos de muertes reportadas en conexión con el tratamiento de Strattera**, se ha enviado para asistir a la agencia en su investigación.

Asimismo, este reporte contiene evidencia de cómo Eli Lilly entregó información falsa y engañosa a la MHRA (en el mes de enero) sobre las muertes relacionadas con el tratamiento de Strattera.

Se puede esperar que los niños y adolescentes que estén recibiendo Strattera "para el TDAH", tengan un estado de salud normal y dentro de este grupo de "pacientes", la morbilidad y mortalidad deberían de ser extremadamente bajas. Este reporte muestra todo lo contrario.

En noviembre del 2007, hice una solicitud de FOIA¹ a la MHRA, sobre el número de personas que habían muerto con el tratamiento de

¹ Nota del Traductor: Derecho de Acceso a la Información [Freedom of Information Act]. En México se conoce como Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental [LFTAIPG].



Strattera. La agencia ni siquiera sabía quién era el fabricante, ni tampoco indagó sobre éste, Eli Lilly.

Eli Lilly anotó en los registros de la compañía (hasta el 30 de noviembre del 2007): **“Habíamos identificado 41 casos de muertes en nuestra base de datos de seguridad”**. Pero, como la compañía sólo acepta las muertes reportadas por “un profesional del cuidado de la salud (HCP) o una autoridad reguladora”, 17 de estos casos fueron eliminados inmediatamente. En las propias palabras de Eli Lilly fueron: **“De los 41, sólo 24 casos fueron debido a Reacciones Adversas a la Droga (ADR) con resultados fatales”**.
[1]

La MHRA no obtuvo más información sobre estos casos de muertes de Lilly, sólo los números.

En una nueva investigación de casos de muertes como resultado del tratamiento con Strattera, se reportaron a la FDA (2004-2007), y un informe crítico de Seguridad Periódica de Reportes Actualizados (PSURs, por sus siglas en inglés) para Strattera, mostró lo siguiente:

Niños y Adolescentes:

31 niños y adolescentes han muerto durante el tratamiento con Strattera, siendo Strattera la Droga en Sospecha Primaria (PS – Prime Suspect). 19 de ellos cometieron suicidio.

Además de los reportes de la FDA, la información en diferentes PSURs en Europa mostró que **6 niños y adolescentes más habían muerto** durante el tratamiento con Strattera.

Adultos:

33 adultos habían muerto mientras estaban bajo el tratamiento con Strattera, y se reportó que Strattera era la Droga en Sospecha Primaria (PS – Prime Suspect). 17 de estos adultos cometieron suicidio.

Además de los reportes de la FDA, la información en diferentes PSURs en Europa mostró que **4 adultos habían muerto** durante el tratamiento con Strattera (por ataque cardíaco).

En los reportes de la FDA también se informó que hubieron **7 casos de mortinato/abortos espontáneos**, informando que Strattera era la **Droga en Sospecha Primaria (PS – Prime Suspect)** .



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Así, la sumarización de los casos de muertes de la FDA 2004-2007 y PSURs es:

37 niños y adolescentes + 37 adultos + 7 mortinatos/abortos espontáneos = 81 muertes.

De estas 81 muertes por lo menos 47 fueron reportadas por los profesionales del cuidado de la salud (HPC).

Para ver información específica sobre los casos fatales que se reportaron a la FDA 2004-2007, vea la tabla ***Strattera Deaths with Strattera as Primary Suspect Drug***

<http://www.psychdrugdangers.com/stratteradeath-new.html> [2], y para TODOS los casos de muertes reportados en el documento adjunto (y enlace) ***StratteraDeath*** <http://jannel.se/StratteraDeath.pdf> [3].

Además, se reportaron a la FDA 2004-2007 los siguientes casos de muertes en conexión con el tratamiento de Strattera – con Strattera como la *Droga en Sospecha Secundaria (SS)* o con *drogas concomitantes (C)*: **4 niños y adolescentes y 10 adultos** [véase también 3].

En total: de FDA 2004-2007 y PSURs incluyendo Strattera en todos los Tipos de Códigos (PS, SS, C):

22 (suicidios) + 19 = 41 niños y adolescentes;

22 (suicidios) + 25 = 47 adultos

+ 7 mortinatos/abortos espontáneos

= 95 casos de muertes

Lilly entregó una cifra de 41 muertes – pero inmediatamente excluyó 17 reportes de casos , y dijo que la cifra que debería usarse era de 24. [1]

Ahora bien, he dado información específica sobre casos de muertes confirmados en conexión con el tratamiento de Strattera. Y el número es mucho más alto que el que reportó Lilly.



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Me refiero a la promesa de la agencia para: **“llevar a cabo cualquier acción necesaria para proteger al público rápidamente si existiera algún problema” [4]**

La información anterior definitivamente se refiere a la existencia de un problema: como se dijo, se puede esperar que los niños y adolescentes que estén recibiendo Strattera “para el TDAH”, tengan una salud normal y en este grupo de “pacientes” deberían de existir una morbilidad y mortalidad extremadamente bajas.

Pero la información anterior dice que 41 niños y adolescentes han muerto en los últimos 5 años mientras estuvieron bajo el tratamiento de Strattera – y 22 de ellos cometieron suicidio.

Agregue a esto el número increíble de casos adversos reportados internacionalmente sobre Strattera (en la mayoría de niños) – Lilly le dijo a MHRA: **“Durante este período informativo, un total de 23,132 reportes de casos adversos espontáneos de atomoxetina [Strattera], representan 58,048 casos adversos, fueron colectados por la MAH [Poseedor de la Autorización de Mercado – Market Authorization Holder, Eli Lilly]. [5]** Esto abarca el período desde noviembre del 2002 a Marzo del 2006. El número de personas que han tenido **tendencias suicidas en conexión con el tratamiento de Strattera ha alcanzado recientemente 965** (PSUR 9, pag. 106). Hasta noviembre del 2007 (PSUR 9, Anexo 16) también hubieron **513 reportes de casos sobre manía, psicosis o alucinaciones en conexión con el tratamiento de Strattera.**

La MHRA no ha tomado ninguna acción manifiesta para proteger a los niños de todos estos efectos dañinos – ni siquiera han contestado informes anteriores sobre las muertes con el tratamiento de Strattera.

Me gustaría obtener una respuesta rápida a estas dos preguntas:

1. ¿Va la agencia a poner en cuestión la información entregada por Eli Lilly (41 muertes, 24 confirmados por un profesional del cuidado de la salud [HCP]) en vista de la evidencia presentada recientemente (81 muertes en FDA 2004-2007 con Strattera como la Droga en Sospecha Primaria y en PSURs, con por lo menos 47 de estas 81 muertes confirmadas por HPCs; y un total de 95 casos de muerte?



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2. ¿Va la agencia (considerando el daño infligido a los niños) a comenzar a hacer una investigación de todos los casos de muerte reportados en conexión con el tratamiento de Strattera?

Atentamente,

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Referencias:

- [1] Eli Lilly, Letter to the MHRA, January 2, 2008, (see last 3 pages)
<http://jannel.se/FOI%2008-011.redacted.letters.Strattera.pdf>
- [2] Psychdrugdangers, *Strattera Deaths with Strattera as Primary Suspect Drug*, (visited May 15, 2008, <http://www.psychdrugdangers.com/stratteradeath-new.html>)
- [3] StratteraDeath, May 15, 2008, <http://jannel.se/StratteraDeath.pdf>
- [4] MHRA, About us, (visited May 15, 2008, <http://www.mhra.gov.uk/Aboutus/index.htm>)
- [5] Eli Lilly, *Main Report*, for Periodic Safety Update Report (PSUR) 6, page 105, period November 27, 2005 through May 28, 2006, http://jannel.se/Mainreport_p105.pdf

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Strattera Deaths with Strattera as Primary Suspect Drug



This table shows all adverse reactions and indications (the condition being treated) reported to the FDA's [Adverse Event Reporting System](#) between 2004 and 2007 where Strattera (atomoxetine) was identified as the Primary Suspect Drug (FDA's term) responsible for causing these reactions in those ISRs (Individual Safety Reports) that had "Abortion Spontaneous", "Cardiac Arrest", "Completed Suicide", "Death" or "Stillbirth" as an Adverse Reaction. Where an Age, Date of Event, Date of Death, Rpt'd By or Indication isn't shown, none was provided in the report.

Rpt'd by: CN-Consumer, LW-Lawyer, MD-Physician, OT-Other Healthcare Provider, PH-Pharmacist, Blank-Not Reported in ISR (Individual Safety Report).



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Rpt Code is the type of report submitted: DIRect reports from Consumers or Doctor to the FDA; EXPeDited reports to the FDA from Eli Lilly; PERiodic reports from Eli Lilly to the FDA.

Reports highlighted in **grey** are DIRect reports that appear to be for the same Case/Event of an adjacent EXPeDited report. The four Completed Suicides in these DIR reports are not included in the Deaths tally.

The 12 Case Reports highlighted in **green** do not contain one of the above Adverse Reactions, but the Outcome for these Events is listed as "Death" and the Date of Death matches the Event Date (or is one day after for Case 5655897 and Case 6234939). These 12 deaths are included in the Deaths tally.

The 4 Case Reports highlighted in **yellow** also have an Outcome of "Death", but their Date of Death is from 4 to 8 days after the Event Date. These 4 deaths are included in the Deaths tally as no other drug is identified as the Primary Suspect for the Outcome, but they may not have been caused by the patient taking Stratterra.

Where a Case number *does* repeat, the Case number is bolded and any repeating Adverse Reactions (Suicides, Deaths, etc) are not added to tallies.

That said, note that Case 5952177 appears in the table twice, once with a Patient Age of 15 and once with an Age of 16. This may be two Cases as the Event Dates for Completed Suicide are different, although those could be a transposition error: **01/01/2005** and **10/01/2005**.

Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
		4148 345	4364 662		05/21/ 2004		Strat tera	X	M D		Anencephal y, Intra- Uterine Death , Transmissio n of Drug Via Semen	EX P
		4148 345	4464 694	04/01/ 2004	09/29/ 2004		Strat tera	X	M D		Abortion Induced, Anencephal y, Drug Exposure During Pregnancy, Transmissio n of Drug Via Semen	EX P
	F	4205 958	4441 500		07/28/ 2004		Strat tera	X		Attention Deficit/Hyp eractivity Disorder	Abortion Spontaneo us	PE R
	M	5744 981	4579 512		02/09/ 2005		Strat tera	X	M D		Completed Suicide	EX P
	F	5764 249	4607 026	02/21/ 2005	03/09/ 2005	02/21/ 2005	Strat tera	X	M D		Death	EX P
	F	5892 273	4786 807	02/21/ 2005	10/03/ 2005	02/21/ 2005	Strat tera	X	CN	Attention Deficit/Hyp eractivity Disorder	Completed Suicide	DI R
	M	5897 087	4789 848	04/28/ 2005	10/05/ 2005		Strat tera	X		Attention Deficit/Hyp eractivity	Completed Suicide	DI R



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Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rp t'd By	Indications	Reactions	Rp t Code
	M	5919 125	4815 742	05/28/ 2004	10/26/ 2005	05/28/ 2004	Strat tera	X			Completed Suicide	EX P
	M	5939 430	4814 268	10/18/ 2004	10/26/ 2005	10/18/ 2004	Strat tera	X			Completed Suicide, Drug Ineffective	EX P
	M	6014 238	4949 708	02/01/ 2006	03/15/ 2006	02/01/ 2006	Strat tera	X	M D	Closed Head Injury	Coma	EX P
		6041 125	4985 900		04/19/ 2006		Strat tera	X	M D		Drug Exposure During Pregnancy, Pregnancy, Stillbirth	EX P
	U n k	6041 125	5022 685	06/01/ 2005	06/05/ 2006	02/18/ 2006	Strat tera	X	M D		Drug Exposure During Pregnancy, Intra-Uterine Death, Labour Complication, Stillbirth	EX P
	U n k	6041 125	5053 558	06/01/ 2005	07/12/ 2006	02/18/ 2006	Strat tera	X	M D		Anoxia, Drug Exposure During Pregnancy, Labour Complication, Stillbirth	EX P
	F	6043 198	4991 479	01/11/ 2006	05/02/ 2006	01/11/ 2006	Strat tera	X	M D	Attention Deficit/Hyperactivity Disorder	Convulsion, Neuroleptic Malignant Syndrome	DI R
	U n k	6045 434	4990 718	02/01/ 2006	04/28/ 2006	02/01/ 2006	Strat tera	X			Drug Exposure During Pregnancy, Stillbirth	EX P
	U n k	6045 434	5053 551	02/01/ 2006	07/12/ 2006	02/01/ 2006	Strat tera	X			Drug Exposure During Pregnancy, Stillbirth	EX P
	M	6168 850	5144 654		10/31/ 2006		Strat tera	X	M D	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EX P
	M	6237 403	5237 339		02/13/ 2007		Strat tera	X	CN		Death	EX P
	M	6371	5401	05/01/	07/31/	05/01/	Strat	X	M	Anxiety	Completed	EX



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			858	716	2007	2007	2007	tera		D		Suicide	P
		F	6508 341	5565 406	01/11/ 2006	12/18/ 2007	01/11/ 2006	Strat tera	X	CN		Death	EX P
3	Ye ars	F	6355 915	5385 850		07/12/ 2007		Strat tera	X	M D		Death	EX P
5	Ye ars	M	4112 478	4319 609	02/01/ 2004	03/16/ 2004	02/01/ 2004	Strat tera	X		Attention Deficit/Hyp eractivity Disorder	Drowning	EX P
5	Ye ars	M	4112 478	4341 947	02/07/ 2004	04/15/ 2004	02/07/ 2004	Strat tera	X	M D	Attention Deficit/Hyp eractivity Disorder	Drowning, Victim of Homicide	EX P
5	Ye ars	M	5882 337	4771 184	08/01/ 2005	09/14/ 2005		Strat tera	X			Accidental Drug Intake By Child, Accidental Overdose, Brain Death	EX P
	Age	M /F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Nam e	Blac k Bo x	Rp t'd By	Indications	Reactions	Rp t Co de
5	Ye ars	M	5882 337	4803 083	08/12/ 2005	10/13/ 2005		Strat tera	X	M D		Accidental Drug Intake By Child, Accidental Overdose, Hypoxia	EX P
5	Ye ars	M	5882 337	4824 283	08/12/ 2005	11/08/ 2005		Strat tera	X	M D		Accidental Drug Intake By Child, Accidental Overdose, Brain Hypoxia, Cerebral Ischaemia, Convulsion, Hypoxia, Musculoskel etal Stiffness, Pupil Fixed, Respiratory Depression, Staphyloco ccal Infection	EX P
5	Ye ars	M	5882 337	4834 985	08/12/ 2005	11/14/ 2005		Strat tera	X	M D		Accidental Drug Intake By Child, Accidental Overdose, Atrophy, Brain Hypoxia, Cerebral Ventricle Dilatation, Convulsion,	EX P



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											Ischaemia, Metabolic Disorder, Musculoskeletal Stiffness, Pupil Fixed, Respiratory Depression, Staphylococcal Infection	
5	Years	M	5882337	4935264	08/12/2005	03/02/2006		Strattera	X	CN	Accidental Overdose, Cerebral Atrophy, Cerebral Ischaemia, Convulsion, Hypoxia, Medication Error, Musculoskeletal Stiffness, Nuclear Magnetic Resonance Imaging Brain Abnormal, Pupil Fixed, Respiratory Depression, Staphylococcal Infection	EXP
6	Years	M	5876785	4765195		09/06/2005		Strattera	X	MD	Cardiac Arrest	EXP
6	Years	M	5876785	4773300		09/16/2005		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	EXP
6	Years	M	5876785	4813560		10/26/2005		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	EXP
											Brain Death, Cardiac Arrest, Cardiac Failure Congestive, Cardiac Valve Disease, Cardiomegaly, Congestive Cardiomyopathy, Dilatation Ventricular,	



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												Haemodynamic Instability, Hypotension, Organ Failure, Therapy Non-Responder	
8	Years	M	4199 197	4432 619	08/09/ 2004	08/20/ 2004	08/09/ 2004	Strat tera	X	M D	Attention Deficit/Hyp eractivity Disorder	Aspiration, Cardiac Arrest , Cough, Dyspnoea, Faecal Incontinenc e, Food Allergy, Sudden Death , Urinary Incontinenc e	EX P
8	Years	M	4199 197	4433 960	08/09/ 2004	08/25/ 2004	08/09/ 2004	Strat tera	X	M D	Attention Deficit/Hyp eractivity Disorder	Aspiration, Cardiac Arrest , Cough, Faecal Incontinenc e, Food Allergy, Respiratory Arrest, Sudden Death , Urinary Incontinenc e	EX P
8	Years	M	4199 197	4455 032	08/09/ 2004	09/17/ 2004	08/09/ 2004	Strat tera	X	M D	Attention Deficit/Hyp eractivity Disorder	Aspiration, Cardiac Arrest , Cough, Dyskinesia, Faecal Incontinenc e, Food Allergy, Respiration Abnormal, Sudden Death , Urinary Incontinenc e	EX P
8	Years	M	4199 197	4476 508	08/09/ 2004	10/13/ 2004	08/09/ 2004	Strat tera	X	M D	Attention Deficit/Hyp eractivity Disorder	Aspiration, Cardio- Respiratory Arrest, Cough, Faecal Incontinenc e, Food Allergy, Respiratory	EX P



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												Disorder, Sepsis, Sudden Death , Urinary Incontinence, Viral Infection	
8	Years		4199197	4512534	08/09/2004	11/24/2004	08/09/2004	Strattera	<input checked="" type="checkbox"/>	OT	Attention Deficit/Hyperactivity Disorder	Aspiration, Cardio-Respiratory Arrest, Faecal Incontinence, Food Allergy, Pneumonia, Sepsis, Sudden Death , Urinary Incontinence, Victim of Child Abuse, Viral Infection	EXP
	Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
8	Years	M	4199197	4517495	08/09/2004	11/30/2004	08/09/2004	Strattera	<input checked="" type="checkbox"/>	MD	Attention Deficit/Hyperactivity Disorder	Aspiration, Bronchitis Chronic, Cardio-Respiratory Arrest, Dyspnoea, Faecal Incontinence, Food Allergy, Lung Infection, Pneumonia, Sepsis, Sudden Death , Urinary Incontinence, Viral Infection	EXP
8	Years	M	4199197	4572167	08/09/2004	02/02/2005	08/09/2004	Strattera	<input checked="" type="checkbox"/>	MD	Attention Deficit/Hyperactivity Disorder	Aspiration, Cardio-Respiratory Arrest, Cough, Drug Toxicity, Dyskinesia, Dyspnoea, Faecal Incontinence, Pneumonia,	EXP



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												Sepsis, Somnolence, Sudden Death , Urinary Incontinence, Viral Infection	
9	Years	M	6164 639	5456 690	06/02/ 2004	09/18/ 2007	06/02/ 2004	Strat tera	X	CN	Attention Deficit/Hyp eractivity Disorder	Asphyxia, Cardiac Arrest	EX P
9	Years	M	6237 403	5241 893	12/01/ 2005	02/20/ 2007	12/01/ 2005	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide	EX P
9	Years	M	6237 403	5271 392	12/05/ 2005	03/21/ 2007	12/05/ 2005	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide , Injury Asphyxiatio n	EX P
9	Years	M	6079 094	5039 400	06/02/ 2004	06/23/ 2006	06/02/ 2004	Strat tera	X	LW	Attention Deficit/Hyp eractivity Disorder	Completed Suicide , Cyanosis, Injury Asphyxiatio n, Loss of Consciousn ess, Vomiting	EX P
9	Years	M	6079 094	5102 041	06/02/ 2004	09/07/ 2006	06/02/ 2004	Strat tera	X	LW	Attention Deficit/Hyp eractivity Disorder	Accidental Death , Aspiration, Electromec hanical Dissociatio , Injury Asphyxiatio n, Vomiting	EX P
9	Years	M	6164 639	5147 049	06/02/ 2004	11/09/ 2006	06/02/ 2004	Strat tera	X	CN	Attention Deficit/Hyp eractivity Disorder	Cardiac Arrest , Injury Asphyxiatio n, Ocular Hyperaemia , Vomiting	EX P
9	Years	M	6164 639	5151 819	06/02/ 2004	11/07/ 2006	06/02/ 2004	Strat tera	X	LW	Attention Deficit/Hyp eractivity Disorder	Accidental Death , Injury Asphyxiatio n, Pupil Fixed, Resuscitatio n, Vomiting	EX P
10	Years	M	5952 974	4867 728	03/01/ 2005	12/22/ 2005	03/01/ 2005	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide , Injury Asphyxiatio n	DI R
10	Years	M	5983 572	4898 978	03/01/ 2005	01/27/ 2006	03/01/ 2005	Strat tera	X	MD		Completed Suicide , Injury	EX P



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Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rp t'd By	Indications	Reactions	Rp t Code			
10	Years	M	5983 572	4948 979	03/01/ 2005	03/15/ 2006	03/01/ 2005	Strat era	X	M D		Asphyxiatio n	EX P		
10	Years	M	6109 466	5076 953	02/02/ 2006	08/07/ 2006	02/02/ 2006	Strat era	X	M D	Attention Deficit/Hyp eractivity Disorder	Accidental Death, Balance Disorder, Injury Asphyxiatio n	EX P		
10	Years	M	6109 466	5089 885	02/02/ 2006	08/23/ 2006	02/02/ 2006	Strat era	X	M D	Attention Deficit/Hyp eractivity Disorder	Accidental Death	EX P		
10	Years	M	6109 466	5097 478	02/02/ 2006	09/01/ 2006	02/02/ 2006	Strat era	X	M D	Attention Deficit/Hyp eractivity Disorder	Accidental Death, Injury Asphyxiatio n	EX P		
11	Years	M	5754 653	4595 538	10/08/ 2004	02/24/ 2005	10/08/ 2004	Strat era	X		Depression	Cardio-Respiratory Arrest	EX P		
11	Years	M	5754 653	4638 248	10/08/ 2004	04/15/ 2005	10/08/ 2004	Strat era	X	M D		Cardio-Respiratory Arrest, Fatigue, Medication Error, Suicidal Ideation	EX P		
12	Years	M	4041 277	4356 760	11/04/ 2003	05/07/ 2004	11/04/ 2003	Strat era	X	M D	Attention Deficit/Hyp eractivity Disorder	Alanine Aminotrans ferase Increased, Aspartate Aminotrans ferase Increased, Blood Uric Acid Increased, Cardiomegaly, Granulocyte Count Decreased, Lymphocyte Count Decreased, Myocarditis, Nausea, Upper Respiratory Tract	EX P		



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												Infection, Viral Infection, White Blood Cell Count Increased	
12	Years	M	4041277	4368795	11/04/2003	05/27/2004	11/04/2003	Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Alanine Aminotransferase Increased, Aspartate Aminotransferase Increased, Atelectasis, Blood Bilirubin Increased, Blood Lactate Dehydrogenase Increased, Blood Urea Increased, Blood Uric Acid Increased, Cardiomegaly, Dilatation Ventricular, Foaming at Mouth, Intracardiac Thrombus, Nausea, Pulmonary Oedema, Upper Respiratory Tract Infection, Viral Myocarditis	EXP
12	Years	M	5910416	4805983	10/23/2004	10/19/2005	10/23/2004	Strattera	X		Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP
12	Years	M	6030367	4973569	10/23/2004	04/13/2006	10/23/2004	Strattera	X	CN	Attention Deficit/Hyperactivity Disorder	Completed Suicide	DIR
12	Years	M	6370501	5400755		07/30/2007		Strattera	X	CN		Completed Suicide	EXP
12	Years		6447235	5493420		10/23/2007		Strattera	X	MD		Death	EXP
14	Years	M	5913951	4806582	09/01/2005	10/19/2005		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide, Injury Asphyxiation	EXP
Age	M	Case	ISR	Date	Recv'd	Date	Drug	Bla	Rp	Indications	Reactions	Rp	



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	/F	#		of Event	by FDA	of Death	Na me	ck Bo x	t'd By			t Co de	
1 4	Ye ars	M	6183 286	5169 928	01/03/ 2005	12/12/ 2006	01/03/ 2005	Strat tera	X	CN	Attention Deficit/Hyp eractivity Disorder	Completed Suicide, Injury Asphyxiatio n	EX P
1 4	Ye ars	M	6315 638	5328 731	01/01/ 2004	05/18/ 2007	05/06/ 2007	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide	EX P
1 4	Ye ars	M	6411 933	5450 107	07/01/ 2007	09/12/ 2007	07/01/ 2007	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Ventricular Fibrillation	EX P
1 4	Ye ars	M	6411 933	5485 865	07/01/ 2007	10/15/ 2007	07/01/ 2007	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Ventricular Fibrillation	EX P
1 4	Ye ars	M	6411 933	5486 349	07/01/ 2007	10/16/ 2007	07/01/ 2007	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Ventricular Fibrillation	EX P
1 5	Ye ars	M	5671 703	4501 050	10/14/ 2004	11/09/ 2004	10/14/ 2004	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide, Injury Asphyxiatio n, Self Injurious Behaviour	EX P
1 5	Ye ars	M	5671 703	4538 814	10/14/ 2004	12/22/ 2004	10/14/ 2004	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Completed Suicide	EX P
1 5	Ye ars	M	5952 177	4860 774	01/01/ 2005	12/16/ 2005		Strat tera	X	MD		Completed Suicide	EX P
1 6	Ye ars	M	3970 831	4501 064	06/12/ 2003	11/09/ 2004	06/16/ 2003	Strat tera	X	MD	Attention Deficit/Hyp eractivity Disorder	Abnormal Behaviour, Acute Respiratory Distress Syndrome, Blood Amylase Increased, Cardiac Arrest, Congestive Cardiomyop athy, Dehydratio n, Dyspnoea, Epistaxis, Headache, Insomnia, Lipase Increased, Listless, Nausea, Pericardial	EX P



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												Effusion, Syncope, Vomiting	
16	Years	M	5671703	4493571	09/01/2004	11/02/2004		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide, Injury Asphyxiation	EXP
16	Years	M	5951902	4860620	01/01/2005	12/16/2005		Strattera	X		Attention Deficit/Hyperactivity Disorder	Completed Suicide, Gun Shot Wound	EXP
16	Years	M	5951902	4861048	01/01/2005	12/16/2005		Strattera	X		Attention Deficit/Hyperactivity Disorder	Completed Suicide, Gun Shot Wound	EXP
	Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
16	Years	M	5951902	4883799	01/01/2005	01/13/2006		Strattera	X	OT	Attention Deficit/Hyperactivity Disorder	Alcohol Use, Completed Suicide, Drug Abuser, Gun Shot Wound, Intentional Self-Injury	EXP
16	Years	M	5952177	4882987	10/01/2005	01/13/2006		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP
16	Years		6322828	5338855	10/03/2004	05/30/2007	10/03/2004	Strattera	X	CN	Disturbance In Attention	Completed Suicide	EXP
16	Years	M	6393534	5429168	01/01/2007	08/29/2007	01/01/2007	Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP
17	Years	M	4152711	4371054	04/01/2004	05/27/2004	04/01/2004	Strattera	X	OT		Completed Suicide	EXP
17	Years	M	4152711	4456276	04/01/2004	09/17/2004	04/01/2004	Strattera	X	MD		Completed Suicide, Injury Asphyxiation, Intentional Self-Injury	EXP
17	Years	M	5738728	4571988	11/11/2004	02/02/2005	11/11/2004	Strattera	X	MD		Completed Suicide, Drug Level Increased, Treatment Noncompliance	EXP
17	Years	M	5738728	4588762	11/11/2004	02/16/2005	11/11/2004	Strattera	X	MD		Completed Suicide, Drug Level Increased,	EXP



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												Parent-Child Problem, Treatment Noncompliance	
17	Years	M	5738728	4613142	11/11/2004	03/16/2005	11/11/2004	Strattera	X	MD		Completed Suicide, Intentional Misuse, Treatment Noncompliance	EXP
17	Years	M	5738728	4709545	11/11/2004	07/07/2005	11/11/2004	Strattera	X	MD		Completed Suicide, Drug Level Increased, Treatment Noncompliance	EXP
17	Years	M	5738728	4847949	11/11/2004	12/06/2005	11/11/2004	Strattera	X	MD	Depression	Completed Suicide, Drug Interaction, Myocardial Infarction, Overdose, Treatment Noncompliance	EXP
17	Years	M	5903501	4797440	05/12/2005	10/07/2005	05/12/2005	Strattera	X	CN		Completed Suicide	DIR
Age		M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
17	Years	M	5924684	4823966	05/12/2005	11/08/2005	05/12/2005	Strattera	X		Disturbance In Attention	Completed Suicide	EXP
17	Years	M	5924684	4870641	05/12/2005	12/28/2005	05/12/2005	Strattera	X		Disturbance In Attention	Completed Suicide, Overdose	EXP
18	Years	M	4168987	4392012		07/01/2004		Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide, Depression, Disturbance In Attention, Emotional Disorder, Gun Shot Wound	EXP
18	Years	M	6026869	4964237	12/14/2005	03/31/2006	12/14/2005	Strattera	X	CN		Completed Suicide, Injury Asphyxiation, Intentional Self-Injury, Skin Laceration	EXP
1	Year		5923	4823		11/07/	01/01/	Strat	X	M		Cardiac	EX



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9	ars		694	523		2005	2004	tera		D		Arrest, Completed Suicide , Multiple Drug Overdose, Respiratory Arrest	P
19	Years	F	5923 694	4938 631		03/06/ 2006	01/01/ 2004	Strat tera	X	M D		Cardiac Arrest, Completed Suicide , Drug Toxicity, Multiple Drug Overdose Intentional, Pulmonary Congestion, Respiration Abnormal, Respiratory Arrest, Somnolenc e	EX P
20	Years	F	5796 217	4655 387		05/05/ 2005		Strat tera	X	OT		Completed Suicide	EX P
20	Years	M	6164 621	5147 021	07/17/ 2004	11/09/ 2006	07/25/ 2004	Strat tera	X	CN		Coma, Injury Asphyxiatio n, Suicide Attempt	EX P
21	Years	M	6054 812	5006 862	01/01/ 2004	05/16/ 2006	09/23/ 2004	Strat tera	X	PH	Attention Deficit/Hyp eractivity Disorder	Completed Suicide , Gun Shot Wound, Head Injury, Intentional Self-Injury, Suicidal Ideation	EX P
21	Years	M	6157 560	5133 886	03/15/ 2005	10/23/ 2006	03/15/ 2005	Strat tera	X		Depression	Completed Suicide , Injury Asphyxiatio n	DI R
22	Years	F	5752 581	4580 254	12/16/ 2003	01/27/ 2005		Strat tera	X	OT	Attention Deficit/Hyp eractivity Disorder	Abortion Spontaneo us	PE R
24	Years	F	5796 217	4713 671	04/27/ 2005	07/13/ 2005		Strat tera	X	OT		Intentional Misuse, Intentional Self-Injury, Overdose, Suicide Attempt	EX P
Age	M /F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Nam e	Blac k Bo	Rp t'd By	Indications	Reactions	Rp t Co	



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									x					de
25	Years	F	6384021	5415914	01/01/2007	08/15/2007		Straterra	X	CN	Attention Deficit/Hyperactivity Disorder	Abortion Spontaneous, Drug Exposure During Pregnancy	EXP	
25	Years	M	6440228	5482913	08/01/2007	10/11/2007		Straterra	X	MD		Completed Suicide	EXP	
25	Years	M	6440228	5565381	08/01/2007	12/18/2007		Straterra	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP	
26	Years	M	5731386	4567102	11/18/2004	01/26/2005	11/18/2004	Straterra	X	MD	Attention Deficit/Hyperactivity Disorder	Drug Toxicity, Hepatic Failure, International Normalised Ratio Increased, Malaise, Overdose, Prothrombin Time Prolonged, Renal Failure, Vomiting	EXP	
26	Years	M	5731386	4576930	11/18/2004	02/08/2005	11/18/2004	Straterra	X	MD	Attention Deficit/Hyperactivity Disorder	Drug Toxicity, Hepatic Failure, Malaise, Renal Failure, Treatment Noncompliance, Vomiting	EXP	
27	Years	M	5899462	4791061	01/01/2005	10/05/2005	01/01/2005	Straterra	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP	
27	Years	F	5996604	4915956	01/01/2006	02/14/2006		Straterra	X	MD		Blood Pressure Decreased, Pyrexia, Tachycardia	EXP	
27	Years	F	5996604	4932051	01/11/2006	02/28/2006	01/11/2006	Straterra	X	MD		Back Pain, Circulatory Collapse, Convulsion, Dizziness, Euphoric Mood, Fall, Lung Infiltration, Neck Pain, Pyrexia, Ventricular	EXP	



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												Fibrillation	
28	Years	M	6183275	5169919	04/13/2005	12/12/2006	04/13/2005	Strat	X	CN		Completed Suicide	EXP
32	Years	F	5651144	4476584	01/01/2004	10/13/2004	01/01/2004	Strat	X	MD		Medication Error, Overdose, Vomiting	EXP
33	Years	F	6373005	5397636	06/25/2007	07/23/2007	06/25/2007	Strat	X		Bipolar Disorder	Completed Suicide, Drug Intolerance	DIR
35	Years	F	4101722	4306022	01/01/2004	02/25/2004	01/01/2004	Strat	X	MD		Completed Suicide	EXP
	Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
35	Years	F	4101722	4373135	06/29/2003	06/03/2004	06/29/2003	Strat	X	MD		Completed Suicide, Contusion, Drug Toxicity, Multiple Drug Overdose	EXP
35	Years	M	4141401	4356942	04/01/2004	05/07/2004	03/08/2004	Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide, Intentional Overdose	EXP
35	Years	M	4141401	4956847	03/08/2004	03/23/2006	03/08/2004	Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Bronchopneumonia, Completed Suicide, Hepatic Steatosis, Intentional Drug Misuse, Multiple Drug Overdose Intentional	EXP
38	Years	F	5752476	4580213	01/01/2004	01/27/2005		Strat	X	CN	Attention Deficit/Hyperactivity Disorder	Abortion Spontaneous	PER
39	Years	M	5744981	4772991		09/15/2005		Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Completed Suicide	EXP
41	Years	M	4157588	4378206	12/19/2003	06/09/2004	12/19/2003	Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Myocardial Infarction	EXP
42	Years	M	6353706	5399156		07/27/2007		Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Death, Sleep Disorder, Somnolence	EXP
4	Ye	F	4148	4364	04/26/	05/21/	04/26/	Strat	X	M	Attention	Agitation,	EX



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5	ars		360	664	2004	2004	2004	tera		D	Deficit/Hyperactivity Disorder	Anxiety, Brain Death, Cardiac Arrest , Loss of Consciousness	P
45	Years	F	4148360	4449074		09/09/2004	04/26/2004	Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Agitation, Anoxic Encephalopathy, Anxiety, Brain Death , Cardiac Arrest, Loss of Consciousness	EXP
45	Years	F	4148360	4456279		09/17/2004	04/26/2004	Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Agitation, Anoxic Encephalopathy, Anxiety, Brain Death , Cardiac Arrest	EXP
46	Years	M	6046261	4991393	04/06/2006	04/28/2006	04/06/2006	Strattera	X	MD		Death	EXP
47	Years	F	5655897	4483431	08/27/2004	10/20/2004	08/28/2004	Strattera	X	MD		Abnormal Behaviour, Contusion, Excoriation, Overdose	EXP
	Age	M/F	Case #	ISR	Date of Event	Recv'd by FDA	Date of Death	Drug Name	Black Box	Rpt'd By	Indications	Reactions	Rpt Code
47	Years	F	5655897	4512529	08/27/2004	11/24/2004	08/28/2004	Strattera	X	OT		Abnormal Behaviour, Contusion, Drug Screen Positive, Overdose, Scratch	EXP
47	Years	F	5655897	4538791	08/28/2004	12/22/2004	08/28/2004	Strattera	X	MD		Abnormal Behaviour, Drug Toxicity, Excoriation	EXP
49	Years	M	6018744	5048538	06/29/2005	07/05/2006	07/06/2005	Strattera	X	MD	Attention Deficit/Hyperactivity Disorder	Loss of Consciousness, Myocardial Infarction, Prescribed Overdose	EXP
49	Years	M	6179782	5164912	06/29/2005	12/05/2006	07/06/2005	Strattera	X	MD	Attention Deficit/Hyp	Coronary Artery	EXP



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											eractivity Disorder	Disease, Coronary Artery Occlusion, Loss of Consciousness, Myocardial Infarction, Prescribed Overdose	
50	Years	F	6234939	5234538	05/09/2006	02/09/2007	05/10/2006	Strat	X	MD	Depression	Drug Toxicity, Gallbladder Disorder	EXP
50	Years	F	6234939	5234546		02/09/2007		Strat	X	MD		Arrhythmia, Drug Interaction	EXP
51	Years	M	6018744	4954842	10/01/2005	03/22/2006	10/01/2005	Strat	X	MD		Death	EXP
51	Years	M	6018744	5022704	07/01/2005	06/05/2006	10/01/2005	Strat	X	MD		Prescribed Overdose	EXP
65	Years	F	5862506	4741355		08/08/2005		Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Adverse Event, Sudden Death	EXP
67	Years	F	5862506	4747181	01/01/2005	08/15/2005	01/01/2005	Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Ejection Fraction Decreased	EXP
71	Years	M	5769652	4898688	01/04/2005	01/27/2006	01/04/2005	Strat	X	MD	Attention Deficit/Hyperactivity Disorder	Acute Myocardial Infarction, Cardiac Arrest , Loss of Consciousness, Ventricular Fibrillation	EXP
76	Years	M	6353706	5383349		07/10/2007		Strat	X	MD		Death	EXP
48 Males			17 Females		71 Cases (Gender was not reported for 6 Cases)			132 Individual Safety Reports					

Completed Suicide/Death Totals									Reported By					
Reaction	SSRs	SNRs	Atypicals	Antidepressants	Antipsychotics	Stimulants	Others	Totals	MD	CN	OT	PH	LW	NR
Completed Suicides:							34	34	31	5	3	1	1	10
Deaths (not from Suicides):							37	37	57	8	4		2	6



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MD = Physician, CN = Consumer, OT = Other Health-Provider, PH = Pharmacist, LW = Lawyer, NR = Author Not Reported.

The Deaths (not from Suicide) tallies are comprised of the Death and Cardiac Arrest/Failure reactions where the Date of Death was not blank and equaled the Event Date (since cardiac arrest may not have resulted in death).

Included in the Deaths (not from Suicide) totals are 4 Spontaneous Abortions (miscarriages). Other types of Abortion (e.g., Abortion Induced) were not included in this tally.

Completed Suicides Reported By Consumer (CN) tallies are what is in the FDA data. Obviously *not* from the consumer (who committed suicide), these reports were likely submitted by family, friends or other associates of the patient.

The Reported By tallies will exceed the Adverse Reaction Totals when there is more than one Individual Safety Report for a Case. The same Adverse Reaction for a Case is not counted twice, but each Reporter is counted.

This is a list of all Primary Suspect Psychiatric Drugs reported in the Detail Table

Strattera (atomoxetine)

These are the Adverse Reactions culled from the Individual Safety Reports where the above Psychiatric Drug was identified as the Primary Suspect Drug

Abnormal Behaviour, Abortion Induced, Abortion Spontaneous, Accidental Death, Accidental Drug Intake By Child, Accidental Overdose, Acute Myocardial Infarction, Acute Respiratory Distress Syndrome, Adverse Event, Agitation, Alanine Aminotransferase Increased, Alcohol Use, Anencephaly, Anoxia, Anoxic Encephalopathy, Anxiety, Arrhythmia, Aspartate Aminotransferase Increased, Asphyxia, Aspiration, Atelectasis, Atrophy, Back Pain, Balance Disorder, Blood Amylase Increased, Blood Bilirubin Increased, Blood Lactate Dehydrogenase Increased, Blood Pressure Decreased, Blood Urea Increased, Blood Uric Acid Increased, Brain Death, Brain Hypoxia, Bronchitis Chronic, Bronchopneumonia, Cardiac Arrest, Cardiac Failure Congestive, Cardiac Valve Disease, Cardiomegaly, Cardio-Respiratory Arrest, Cerebral Atrophy, Cerebral Ischaemia, Cerebral Ventricle Dilatation, Circulatory Collapse, Coma, Completed Suicide, Congestive Cardiomyopathy, Contusion, Convulsion, Coronary Artery Disease, Coronary Artery Occlusion, Cough, Cyanosis, Death, Dehydration, Depression, Dilatation Ventricular, Disturbance In Attention, Dizziness, Drowning, Drug Abuser, Drug Exposure During Pregnancy, Drug Ineffective, Drug Interaction, Drug Intolerance, Drug Level Increased, Drug Screen Positive, Drug Toxicity, Dyskinesia, Dyspnoea, Ejection Fraction Decreased, Electromechanical Dissociation, Emotional Disorder, Epistaxis, Euphoric Mood, Excoriation, Faecal Incontinence, Fall, Fatigue, Foaming at Mouth, Food Allergy, Gallbladder Disorder, Granulocyte Count Decreased, Gun Shot Wound, Haemodynamic Instability, Head Injury, Headache, Hepatic Failure, Hepatic Steatosis, Hypotension, Hypoxia, Injury Asphyxiation, Insomnia, Intentional Drug Misuse, Intentional Misuse, Intentional Overdose, Intentional Self-Injury, International Normalised Ratio Increased, Intracardiac Thrombus, Intra-Uterine Death, Ischaemia, Labour Complication, Lipase Increased, Listless, Loss of Consciousness, Lung Infection, Lung Infiltration, Lymphocyte Count Decreased, Malaise, Medication Error, Metabolic Disorder, Multiple Drug Overdose, Multiple Drug Overdose Intentional, Musculoskeletal Stiffness, Myocardial Infarction, Myocarditis, Nausea, Neck Pain, Neuroleptic Malignant Syndrome, Nuclear Magnetic Resonance Imaging Brain Abnormal, Ocular Hyperaemia, Organ Failure, Overdose, Parent-Child Problem, Pericardial Effusion, Pneumonia, Pregnancy, Prescribed Overdose, Prothrombin Time Prolonged, Pulmonary Congestion, Pulmonary Oedema, Pupil Fixed, Pyrexia, Renal Failure, Respiration Abnormal, Respiratory Arrest, Respiratory Depression, Respiratory Disorder, Resuscitation, Scratch, Self Injurious Behaviour, Sepsis, Skin Laceration, Sleep Disorder, Somnolence, Staphylococcal Infection, Stillbirth, Sudden Death, Suicidal Ideation, Suicide Attempt, Syncope, Tachycardia, Therapy Non-Responder, Transmission of Drug Via Semen, Treatment Noncompliance, Upper Respiratory Tract Infection, Urinary Incontinence, Ventricular Fibrillation, Victim of Child Abuse, Victim of Homicide, Viral Infection, Viral Myocarditis, Vomiting, White Blood Cell Count Increased

Top 10	
Reaction	Cases
Completed Suicide	34



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Injury Asphyxiation	13
Death	8
Cardiac Arrest	7
Overdose	6
Drug Toxicity	6
Vomiting	5
Myocardial Infarction	5
Loss of Consciousness	5
Intentional Self-Injury	5

<http://www.psychdrugdangers.com/stratteradeath-new.html>



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