



Stevens Johnson Syndrome Foundation

Newsletter
June, 2006

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Surviving SJS Documentary

The documentary is now available to physicians and patients who want to learn more about the affects of Stevens Johnson Syndrome (SJS), Surviving SJS includes interviews with doctors and patients while focusing on the story of SJS survivor John Mowatt harrowing experience of contracting SJS from antibiotics taken following heart surgery and his treatment at the Grossman Burn Center in Sherman Oaks, Calif.

Surviving SJS is available in two versions; a 20 minute version for \$29.95 which is recommend by the Stevens Johnson Syndrome Foundation and an expanded one hour version for \$39.95. To purchase either film, contact Diane Cignoni at dcignoni@groundhero.com or call 323-938-3117

SJS Survey forms

As of April 11, 2006 the Stevens Johnson Syndrome Foundation now has 650 completed online surveys. After reviewing the data we have concluded that more females have been afflicted with SJS then male. Almost any medication including over the counter ibuprofen products can trigger SJS.

59 cases were to over the counter ibuprofen, these products are readily available to the public without prescription and carry no warning of SJS.

71 cases were anticonvulsant drugs. Of the 71, 36 cases were to Lamotrigine also known as (Lamictal). This is an anticonvulsants drug being used to treat bipolar disorder. It is

Mandatory Allergic Reaction Reporting in America

Farrell, Anne

Mandatory Allergic Reaction Reporting in America Farrell, Anne 3 May 2006

Two definitions of the word rare may be found in the Merriam Webster dictionary. 2 a : marked by unusual quality, merit, or appeal :and 3 : seldom occurring or found. At age twelve, Molly Claybaugh fit these characteristics. A tap dancer, Molly auditioned among hundreds and was one of the few chosen to participate in the opening ceremony of the 1996 Olympic Games and was also selected as a contestant for Show Stoppers national dance competition. Just two weeks

not recommended for children under the age of 16 as it carries a black box warning of Stevens Johnson Syndrome and a higher incidence of SJS to this drug has been reported in children. In 1997 a "Dear Healthcare" letter was sent by the manufacturer to physicians advising them of this warning. <http://www.fda.gov/medwatch/safety/1997/lamict.htm> Yet, despite this warning, numerous cases of Stevens Johnson Syndrome in children have been reported to the foundation including one child as young as 6 years old.

The rest of the surveys include antibiotics and prescription Non Steroidal Anti-Inflammatory Drugs (NSAIDs)

Topping the list are sulfa based drugs with 184 cases reported.

As you are aware the survey form is voluntary and has only been available for the past 2 years. Each day the SJS Foundation receives at least 3 new completed forms. We are asking all SJS/TEN patients to please complete the survey. This data will help aid in dismissing the RARE word from SJS. In addition we are hoping it will prompt medical schools to rethink their curriculum to include more time on the subject of Stevens Johnson Syndrome. If you have completed the SJS survey thank you for your assistance. To complete the survey please visit <http://www.sjsupport.org/sjsurvey.shtml>

Sponsor an SJS 5K Walk/Run

Please help raise awareness into the signs of Stevens Johnson Syndrome, by sponsoring a 5K walk/run in your area. SJS Walk Buttons are available through [\[click here\]](#)

Other walk items include t-shirts, caps and tote bags. You can also download the SJS Fact Sheet for printing by visiting the SJS Website link at: [\[click here\]](#)
Please copy and distribute them to your walk participants.
[\[more\]](#)

before Molly was scheduled to leave she became ill with a fever and the doctor prescribed children's Advil to bring it down. Within eight hours of receiving the drug Molly was diagnosed with Stevens Johnson Syndrome (SJS), a rare, allergic drug reaction. Today as a result of her battle with SJS, Molly is blind, paraplegic, and living on a feeding tube.

The term rare has relative meaning. To Molly's mother her daughter was gifted with a talent that was taken away in a split second. In America severe allergic drug reactions, like the one Molly had been diagnosed with, are considered rare, so rare that it is not necessary to understand exactly how often they occur. Allergic drug reactions are both deadly and commonly occurring and therefore must be reported, something that is not being done regularly today.

The U.S. Food and Drug Administration does not at this time have any type mandatory allergic reaction reporting. MedWatch, the current system in place, is a voluntary reporting system that allows consumers and health care professionals to report serious problems with medical devices they dispense or use. Reporting may be done online at the FDA website, via telephone or postal mail. The MedWatch system is not only difficult to navigate, but it is also almost impossible to understand. The information gathered by MedWatch is posted online under cryptic subheadings that give no clue to the medications they are referencing. In a letter to the Stevens Johnson Syndrome Foundation President, Jean McCawley, Dr. Steven Galson, director of the Center for Drug Evaluation and Research states "it would not be feasible nor enforceable to mandate over-the-counter setting" but later suggests in the same letter that if consumers wish to take a larger role in adverse reaction reporting they must report all reactions, including over the counter, through the Mediwatch system (Galson).

This type of reporting is ineffective at informing both consumers and medical professionals of severe reactions that may be caused by both prescribed and over-the-counter drugs. Just last week in New Zealand a call for mandatory

August is SJS Awareness Month!

Your help is needed. As many of you are probably aware, August is Stevens Johnson Syndrome Awareness Month. Once more we are calling on you to help get the word out about SJS. We need volunteers to write to your local governor on behalf of the SJS Foundation, requesting a state proclamation, declaring August as SJS Awareness Month.

Each year we write to all 50 states and each year we have had several new states join us. However, many states will only issue a proclamation if they receive a letter from a resident of their state. Your assistance is greatly appreciated.

To view a sample letter please visit
http://www.sjsupport.org/htmldata/sample_governor_letter.html]

Search Engine that donates!

Now there is a new way to help support the Stevens Johnson Syndrome Foundation just by searching the Internet with goodsearch.com. This is a search engine powered by yahoo. All you will need to do is go to www.goodsearch.com and identify Stevens Johnson Syndrome Foundation as your chosen charity. Each time you conduct a search the Stevens Johnson Syndrome Foundation will receive 1 cent. There is no charge to you! Every time you search we get pennies from goodsearch.com and those pennies add up!

So help support the Stevens Johnson Syndrome Foundation while your working or doing homework. Tell your friends and family too! Your support as always is appreciated!
www.goodsearch.com

Dental Problems as a result of SJS

reporting was published in Financial Times Information asking for mandatory reaction reporting as result statistics from last year stating that more then 20,000 patients suffered severe allergic reactions in the last year. The source stated in the article, Sue McKedgley, an MP for the Green party, pointed out that while "the large figures were alarming, they could in fact be much higher as there is no mandatory reporting of adverse drug reactions" (Call for...). Canada and the United Kingdom have both recently developed programs that allow the reporting of allergic reactions to occur swiftly and the information reported to then be made readily to the public.

The UK for instance uses a program enacted by the Commission on Human Medicines called The Yellow Card Scheme. The Yellow Card Scheme is a voluntary program that uses data collected from both patients and medical professionals to record reactions related it prescription medications, herbal remedies, and over-the-counter medications. The scheme has been in use for over 40 years and over 50,000 reports have been collected in that time. Those who report allergic reactions are sent a letter of acknowledgment giving the identification number of the report. Information given in a Yellow Card report is then assessed to determine if a casual relationship exists the drugs and the reaction received. If necessary, changes are made to the labeling of the medication as well as recommendations to increase benefits of the while also minimizing the risks. With this method of reporting patient confidentiality is maintained by both keeping the data received held securely and avoiding storing the patient data with the reaction information itself. A number is assigned to the patient and all further reference to the patient themselves is done via that number. Following analysis Yellow Card data is then made available to the public online and can be downloaded by both medical professionals and patients themselves (Yellow Cards Explained to Public).

In a paper published in September of 2005 Health Canada explains that they have felt it necessary to create a mandatory reaction reporting system due to the feeling that

Often we have had reports from SJS patients complaining of loss of enamel on their teeth. If you have experienced similar problems since SJS please contact the SJS Foundation. We are compiling information on SJS side-effects.

We have also had several reports of children that had SJS before age 5 that are missing permanent teeth under their baby teeth. Dentists have told us this is genetic. It seems more than coincidence that we have several children that had SJS as infants that have this same condition. If your SJS child has missing permanent teeth please contact us at sjsupport@aol.com

estimated reporting rates are as low as one percent (Health Canada Consultation...). Under reporting a problem of this nature has the possibility to cause an under estimate of the severity of a severe health problem. One example of under reporting can be seen recently with severe allergic reactions related to Children's Motrin and other ibuprofen type NSAIDS. In 2004 the Julie Foundation received 12 reports of severe reactions related to the use of Children's Motrin, several resulting in death and severe disabilities of the patients. Within the first two weeks of 2005 two reports of severe reactions were reported to the Julie Foundation. At this rate the amount of children killed or severely disabled as a result of the use of Children's Motrin was likely to double within a year (McCawley). Without actual records of the number of reactions occurring from specific medications there is no way to regulate the removal of hazardous medications until after many patients have died.

Opponents of mandatory reporting cite both a breach of patient confidentiality and concerns about legal liability as reasoning to not enforce the reporting of allergic reactions. "The problems associated with reports are well-known: poor quality of submitted reports; significant underreporting of adverse reactions; difficulty in calculating rates because of incomplete numerator data along with unreliable denominators; and limited ability to establish cause and effect. (Lexchin)." Lexchin continues to state that nearly half of all Canadian medical professionals view reporting as a burden, adding additional required paperwork to an already extremely large work load. Many doctor's view additional paperwork as a burden to their profession drawing them away from their actual patients (McCawley).

The necessity to require mandatory reporting can be further stressed by noting the statistical facts surrounding medical professionals and their knowledge of allergic reactions. In a study done by Health Canada, it was found that 63 % of physicians and 44% of nurses do not understand how to report an allergic reaction. The Julie Foundation for allergic drug reactions also states that 80 % of allergic reactions are

turned away from medical treatment 2 – 5 times before their reaction is diagnosed.

The voluntary system in place is not effective because the information received is coming from the patients themselves, a source that is not taken seriously, according to Jean McCawley, president of the Julie Foundation. McCawley suggests that reports be recorded by the attending doctor or hospital the patient is treated at. Currently allergic reactions are not recorded as a cause of death. Severe reactions are often recorded on death certificates as other causes such as multi-system organ failure or septic shock usually leaving the reaction off the certificate completely. With this manner of record keeping the only way to discover a patient had a severe reaction is to review their chart breaching patient confidentiality completely. In America doctors are being allowed to literally bury their mistakes leaving no record severe reactions (McCawley).

One solution, suggested by McCawley, is to create a new branch of the FDA to monitor severe reactions. The Mandatory Adverse Event Reporting Association or MAERA could be created easily without the addition of much paperwork. Upon the discharge of the patient or time of death the hospital or attending physician would be required to fill out a short form listing the name of the offending drug, ethnic background of the patient and name of the reaction. This information could then be put into a database and analyzed weekly to catch any casual relationships between specific medications and severe reactions. This would allow the FDA to make timely decisions about sudden increases in reactions.

Mandatory reaction reporting would allow medical professionals to see a true estimate of how often these rare reactions occur and would give patients the opportunity to seek and receive proper medical attention at the onset of the reaction. Allergic drug reactions are the third leading cause of death in the United States where death could be avoided in many cases by early treatment and removal of the offending

drug (The facts about SJS).

The United States has clearly fallen behind other world leaders such as the United Kingdom and Canada in regulating the adverse reaction reporting. Now is the time for Congress to push the FDA into creating legislation that will protect American's from medications that are intended to save their lives but sometimes instead results in killing or severely injuring them. Doctors vow to "First do no harm" but cannot prevent harm from their patient without conclusive evidence of possible reactions from prescribed medications. Foreign policies currently in place such as the Yellow Card Scheme may be easily altered for use for the United States through the creation of the MAERA. Allergic drug reactions are not something that will disappear in time, only with mandatory reaction reporting will survival and diagnosis rates will rise in America.

Works Cited

Achieving a Mandatory System for Reporting Serious Adverse Reactions. Health Canada. Health Canada, 2005. 12 Apr. 2006 http://www.hc-sc.gc.ca/index_e.html.

"Call for Mandatory Reporting of Medical Mistakes." Financial Times Information (2006). Lexis Nexis. Morgan Library, Fort Collins. 1 May 2006.

"Court Holds Doc Guilty of Negligence." Mid-Day 8 Feb. 2006. 30 Mar. 2006
<http://ww1.mid-day.com/news/city/2006/february/130415.htm>.

Galson, Steven. 6 Jan. 2004. FDA, 2005.

"Health Canada Consultation on Mandatory Reporting of Adverse Reactions." Canadian Nurse Nov. 2005.

McCawley, Jean. Personal Interview at 9285 N. Utica Street. 6 April 2006.

"Pharmacists Report a Fifth of Adverse Drug Reactions Sent to MHRA." The Pharmaceutical Journal (2006).

"The Facts About Stevens Johnson Syndrome." The Stevens Johnson Syndrome Foundation. 2001. Julie Foundation for

Allergic Drug Reactions. 26 Mar. 2006
<http://www.sjsupport.org>.
"Yellow Cards Explained to Public." Chemist & Drugist 19
Nov. 2005: 14. .

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