

September 2015

Dear :

Here's a recap of blog posts and other news from the past month.

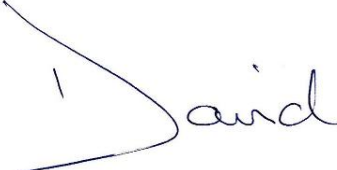
Last week's publication of [Restoring Study 329](#) in The BMJ shows how controlled trials have become the gold standard in hiding adverse events.

Building on this, it will be important to Restore other trials, but of even greater importance is Restoring validity to the experience of patients and doctors reporting adverse events. We are not just anecdotes. [RxISK](#) is the natural partner of the [RIAT process](#). We would hope any of you who have ideas about how to Restore a voice to the voiceless will contribute your ideas to what is happening at RxISK.

There will be a series of RxISK developments rolled out in coming weeks.

Thank you for your support.

Your feedback, as always, is greatly appreciated.



In the news...

[BMJ Publishes Study Revealing How Flawed Drug Research Fails a Trusting Public](#)

Band of Intrepid Researchers "Sets the Record Straight" on Ghostwritten Study

Toronto (16 September 2015) - Today the BMJ published Restoring Study 329, a decade-long effort by researchers to uncover the truth about the safety of an antidepressant approved for use by adolescents. Restoring Study 329 is a reanalysis and rebuttal of the original Study 329...



RxISK stories

[Study 329](#)

RxISK's last story A 329 Story, featured a young woman who went on Paxil soon after the Keller et al version of 329 was published. We would love to hear more from anyone who was put on an SSRI during ... [\[Read More...\]](#)...»

[A 329 Story](#)

This is an account from someone who went on paroxetine - Paxil - Seroxat - soon after Study 329 came out. She didn't commit suicide. But it would be difficult to describe these effects of the drug as good. ... [\[Read More...\]](#)...»

[Benzodiazepine and Antidepressant Dependence](#)

Sally MacGregor has written about the horrors of

dependence on olanzapine - see Olanzapine Withdrawal and back in Olanzapine Waters. Here she picks up a conundrum - Primary Care Doctors react to the idea of Benzodiazepines as though they have been ... [Read More...][...»](#)

[Kicking Lyrica](#)

This post was put together by Johanna Ryan from reports to RxISK on Lyrica - Pregabalin. Lyrica is closely related to Neurontin. Many anticonvulsants such as carbamazepine have been used for forty years for pain syndromes such as ... [Read More...][...»](#)

[The Maintenance Man: Fata-nomics the cancer plaguing healthcare](#)

"You murdered my dad. You poisoned him. You tortured and murdered my dad." The sentencing hearing for Farid T. Fata, M.D. at the federal courthouse in Detroit last week did not ... [Read More...][...»](#)



From David's blog...

[Study 329: MK, HK, SK, GSK & History](#)

What Happened to those Suicidal in Study 329? In May 2014, the RIAT team asked GSK what the children who became suicidal in the course of Study 329 have since been told. (Marty Keller's "take" on this is at the bottom). The consent form says that anyone entering the study would be treated just the [...][...»](#)

[Study 329: MK, HK, SK and GSK](#)

The Letter below from Marty Keller and colleagues was sent to many media outlets, to retraction watch, and to

professional organizations on Wednesday. Paul Basken from the Chronicle for Higher Education asked me for a response which I sent about an hour after receiving the letter. This response is from me rather than the 329 [...]...»

[Study 329](#)

Study 329 has just gone live. The Restoring Study 329 article with its appendices, data, history, accompanying feature by Peter Doshi and editorial by David Henry can be found on the Restoring Study 329 site Study329.org. Here are the key findings at present. Efficacy Harms Background At Present The note above says "Here are the [...]...»

[Study 329: The Data](#)

The text below reproduces the latest page from the Study329.org site. The links mentioned here will become live on the site once Restoring Study 329 is published late Wednesday - early Thursday next week. In 2004 as part of the resolution of a fraud action taken by New York State, GlaxoSmithKline agreed to post [...]...»

[The Troubled Life of Study 329: Consequences of Failure to Retract](#)

If someone were to ask the surviving authors of Study 329 the question: "Knowing what you know now, if you had to do it over, would you agree to participate in that study again?", many would probably say no. The real title of Study 329 was "Efficacy of Paroxetine in the Treatment of Adolescent Major [...]...»

[Original Study 329 Team](#)

MARTIN B. KELLER, M.D. Brown University Martin B. Keller Professor Emeritus of Psychiatry and Human Behavior Martin_Keller@brown.edu Martin Keller has made major research contributions to the understanding and treatment of mood disorders. He has performed research on the longitudinal course and neuropsychopharmacology of affective disorders and anxiety disorders and on the [...]...»

[Study329.org: Science with a Conscience](#)

Faced in 2012 with questions about the \$3 Billion fine imposed on GSK - triggered by a sequence of events starting with Study 329, - is it just the cost of doing business? Andrew Witty snapped back: "Although corporate malfeasance cases end up looking very big, they often have their origin in just... one or [...]...»

[Study 329: The Timelines](#)

In addition to hosting the Panorama programs and The Famous Grouse history of Study 329, Study329.org has a comprehensive timeline on the origins of concerns about the SSRIs and the risk of suicide - initially with Prozac and subsequently with Paxil - Seroxat. The chronology is laid out year on year with key documents linked [...]...»

[Study329.org: The Panorama Files](#)

Study 329 is probably the most famous clinical trial ever. It is one of the few to attract a Fraud action and is certainly the only one with a \$3 Billion fine linked to it. See A Milestone in Drug Safety. The study began recruiting adolescents to Paxil, imipramine or placebo in 1994 and finished [...]...»

[A Milestone in the Battle for Truth in Drug Safety](#)

Study 329: The final chapter coming soon Arguably the most controversial drug study ever, Study 329, published in July 2001: Concluded that paroxetine was a safe and effective medication for treating major depression in adolescents; Is still widely cited in the medical literature, providing physicians with assurance about the usefulness of paroxetine; Was criticized by [...]...»



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