

Re: Postmarketing surveillance must change

Source: <http://sci.tech-archive.net/Archive/sci.med/2004-12/0085.html>

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Date: 11/22/04

Date: Mon, 22 Nov 2004 05:06:08 -0500

"outrider" <outrider@despammed.com> wrote in message
news:1101075465.961211.240490@c13g2000cwb.googlegroups.com...

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> *JAMA Editors Call for Major Restructuring of Postmarketing Surveillance
> System*

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> *CHICAGO – In an editorial in the December 1 issue, JAMA
> Editor-in-Chief, Catherine D. DeAngelis, M.D., M.P.H., Executive Deputy
> Editor, Phil B. Fontanarosa, M.D., and Deputy Editor Drummond Rennie,
> M.D., write:*

>

> *"Physicians and patients expect that when medications are prescribed
> correctly for labeled indications and are used as directed, these
> medications generally will have beneficial effects and will not cause
> significant harm.*

Generally will have? *Significant* harm? Can this mean that physicians
and patients do not expect 100% effectiveness 100% of the time and do not
expect drugs to be 100% safe 100% of the time? Who would have thought it?

> *This confidence in pharmaceutical products reflects
> trust in the effectiveness and integrity of the drug approval and
> monitoring process. However, the current approval process for drugs
> and biological agents in the United States has come under intense
> scrutiny, most notably because of concerns about influence from
> industry."*

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> *"To improve the necessary measures to monitor the safety of marketed
> drugs, the drug approval process must be decoupled from the
> postmarketing safety and surveillance system. It is unreasonable to
> expect that the same agency that was responsible for approval of drug
> licensing and labeling would also be committed to actively seek
> evidence to prove itself wrong (i.e., that the decision to approve the*

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> *product was subsequently shown to be incorrect.*)

Hmmm.... If a decision is made based upon evidence sets A, B, and C, and subsequent to the decision, evidence set D becomes available, was the person or organization incorrect in making the decision, or was the person or organization making the decision wrong? Seems to me that the *decision* turns out to be wrong, but the person or organization who made the decision was not incorrect when the decision was made and the decision, when made, wasn't wrong.

A fine point to be sure, and it may well be that in the realm of pharmaceuticals, there should be separate organizations charged with drug approval and subsequent surveillance of the drug to insure safety. But the implication that this would necessarily improve product safety is not logical. Some drugs genuinely believed to be safe based upon honest evaluation of statistically significant evidence adduced prior to approval and evaluated during the approval process will continue to be approved for dissemination, and will continue to turn out to be dangerous after the product is marketed and is used (and misused/abused while required patient monitoring is neglected). Increasing the sample size guarantees this.

> *One option worth*

> *strong consideration, as others have suggested, is to establish an*
> *independent drug safety board or independent agency for drug safety,*
> *specifically to oversee postmarketing surveillance for drugs and*
> *devices." ... "Above all, the agency must be completely independent*
> *of influence from the pharmaceutical industry, biotechnology firms, and*
> *medical device manufacturers."*
>

Probably an improvement. Not necessarily a complete cure for the problem.

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> *"The postmarketing surveillance system requires a long overdue major*
> *restructuring. Until that occurs – as indicated by the articles in*
> *this issue of JAMA, as epitomized by recent evidence of serious harms*
> *from widely used and heavily promoted medications, as demonstrated by*
> *the influence of industry over postmarketing data, and as illustrated*
> *by the lengths to which some manufacturers will go to protect their*
> *interests – the United States will still be far short of having an*
> *effective, vigilant, and trustworthy system of postmarketing*
> *surveillance to protect the public."*

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> *(JAMA. 2004;292: 2647 – 2650)*

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Steve

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represent the opinion of my employer, but is merely my personal view. To reply, delete `_spamout_` and replace with the numeral 3