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UnInformed Consent

"Breach In Patient Confidentiality" Allegations by CDC "Baseless" and "Disingenuous" Say Congressional Investigators

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For Complete In-Depth Coverage and Stats of US National Academy of Sciences Continuing Investigation…
http://www.universityofhealth.net/NAS/NAS%20Roster.htm

UNINFORMED CONSENT, SEATTLE, WA – Days after congressional investigators testified their disturbing findings of the CDC's VAERS database before the US National Academies of Sciences, (NAS), Immunization Safety Review Committee, (ISRC), the CDC, (Centers for Disease Control), wasted no time in accusing the investigators of "potential breaches in confidentiality" while examining the CDC's VAERS, (Vaccine Adverse Effects Reporting System) database on vaccine safety. The CDC then barred the investigators from future access. See Complete Coverage of NAS Hearing

The CDC allegations were the subject of a letter written by Jeanne Santoli MD, CDC's Acting Assoc. Director For Science. The letter was addressed to Leigh Pruneau, PhD RN, IRB Administrator of Northern CA Kaiser a large HMO in California. Santoli claimed the researchers conducted "unapproved analyses" on their datasets and could have "increased the risk of a confidentiality breach." See CDC/Geier letters

In addition to the researcher's categorical denial of "these baseless allegations," in a detailed 3-page response addressed to Pruneau, Dr. Mark Geier and David Geier called the CDC allegations "disingenuous" since they have yet to finish their analysis. The letter also outlined the CDC's stringent requirements for them to access the database and how the information was made available. The letter states in part: See Geier Response.

" the datasets…(sic)…contain no names, addresses, zip code, state of residence, phone number, HMO membership information or center of examination…"

"Patients are identified by an encrypted randomly assigned patient number that is different for each dataset."

In addition, the researchers described how:

- Each person granted access was assigned a full time "monitor" "to stand full time guard."
- The access computer disk drive was disabled during their viewing time.
- Print outs were printed in another locked room where "a completely independent staff member was the only one with access.
- This independent staff member passes any print outs to the monitors who obliterate any information that may endanger patient confidentiality.
- The monitors then photocopy these printouts to ensure their blackouts are irreversible.

In contrast to their experiences as congressionally commissioned investigators, the letter goes on to describe that if a researcher is part of the VSD, (Vaccine Safety Datalink), "team", they have very different freedoms. A VSD team researcher can access all data freely including downloading data and removing it from the RDC, (Research Data Center where the records are held), with minimum patient confidentiality protection). Further, the VSD team researchers do not have to obtain IRB, (Institutional Review Board), approval for studies.

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The CDC allegation that investigators attempted to rename files was a potential error in the system and brought to the attention of the CDC by the investigators themselves.

The outside CDC investigation was commissioned by Congress almost two years ago to review the VAERS data after 1000's of parents have claimed their children were disabled, maimed or died after their inoculations. Parents claim egregious

conflicts of interest within governmental agencies charged with monitoring safety and individuals within these agencies receiving millions of dollars from pharmaceutical interests to turn a blind eye to approval of vaccines and medications that may to be dangerous.

The CDC finally granted the first access to the investigators in October of 2003 after two years of continual roadblocks. A second access was granted in January of 2004.

The Vaccine Adverse Event Reporting System is a cooperative program for vaccine safety of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of US licensed vaccines.

Critics claim this latest in a series of government agencies lack of transparency and avoiding public exposure is tantamount to weapons inspectors being denied access to Iraq until Saddam has had enough time to hide the evidence.

See NAS video clips of experts and disclosures

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