NIH Secrets Government Funded Data Concealment_Lenzer-New Republic

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An eye opening article by Jeanne Lenzer, “NIH Secrets,” in The New Republic (below), should make the new Congress sit up and take notice!

If you thought that there was all that much difference between the concealment of data by investigators conducting pharmaceutical-sponsored clinical trials and trials funded by the National Institutes of Health, think again.

Taxpayers are footing the bill for research studies whose data is kept secret—despite a 1999 law requiring government grant recipients to share the data. [1] The Shelby Amendment specifically directs federal agencies to "ensure that all data" from federally funded research are "made available to the public through the Freedom of Information Act." The NIH, in its data-sharing guide known as Circular A-110, asserts that data-sharing "is essential ... to improve human health."

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Lenzer cites several examples of data concealment that resulted in serious consequences—including the adoption of harmful treatment guidelines. For example, each year, approximately 10,000 people, most of them young and healthy, suffer spinal-cord injuries in car accidents, falls, or shootings. In 1990 NIH announced with great fanfare the findings of a 487-person trial that appeared to show that high-dose steroids reduced paralysis caused by acute spinal cord injury. The announced findings were followed up with a “Dear Doctor” letter to all emergency care doctors. Six weeks later the study, headed by Michael Bracken of the Yale School of Public Health, was published in The New England Journal of Medicine.

The problem is physicians treating patients with spinal chord injury are skeptical because they are finding MORE deaths among patients treated with high dose steroids. But all Freedom of Information requests to Dr. Bracken, Yale, and NIH for the trial data have been flat out denied. The same refusal occurred when data was requested from taxpayer funded pediatric SSRI antidepressant trials.

Industry’s overwhelming influence spills over into government funded research. As Lenzer notes: “individual researchers--including some who have refused to release their data in response--have also received funding from sponsoring drug companies. These commercial ties, and the secrecy they spawn, have real consequences for physicians who must rely on research results that may not be entirely disinterested.”

Government sanctioned secrecy protects commercial interests. The de facto policy provides confirmatory evidence that the scientific method whereby research findings must stand the test of independent replication or refutation is dead and buried in a casket bearing the government seal. Industry calls the shots: FDA, NIH, and academics at prestigious institutions serve as its willing paid sycophants. The drug industry has tainted science, unleashed lethal drugs on the market bearing the government seal, and has de facto taken the reins of regulatory control for the entire enterprise.

Lenzer’s review of “all of the grants awarded by the NIH during 2005 and finding that virtually none of the data would fall under the conditions of mandatory release, I asked the NIH to identify any studies that had been released under the Shelby Amendment. Their answer was surprisingly frank: I was told that, "despite numerous requests" for data since the Shelby Amendment was passed in 1999, "none met the criteria of the regulation."

Only Congressional action is capable of restoring integrity to medical science.

1 . See: U.S. Office of Management and Budget Circular A-110, effective Nov. 8, 1999
http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

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It's not news that the pharmaceutical industry routinely suppresses negative data, with the effect of exaggerating the benefits of its drugs and glossing over their risks. Take, for example, the painkiller Vioxx. According to court testimony, the drug's manufacturer, Merck, withheld data showing that the drug caused five times as many heart attacks as a similar painkiller, naproxyn. The result? Food and Drug Administration (FDA) safety expert David Graham calculated that Vioxx caused an estimated 39,000 to 60,000 heart-attack deaths before it was pulled from the market in 2004. Or take the example of the anti-depressants known as SSRIs, which include Prozac and Paxil. Recent analyses of several papers touting the benefits of the drugs for children found that the authors had accentuated the positive and downplayed the negative. It was only when the FDA analyzed all the data, in a 2004 study that was initially suppressed, that it was discovered that taking the drugs doubled the risk of suicide for young people.

Thank goodness these secretive, corporate drug trials are counterbalanced by taxpayer-funded studies at the National Institutes of Health (NIH), whose results are open to public scrutiny, right?

Actually, wrong. You would think that, because taxpayers paid for the studies, the data ought to be available for independent verification. But that's not how it actually works. When several leading researchers contacted me, frustrated because they couldn't obtain data from NIH-funded studies, I filed Freedom of Information Act (FOIA) requests for the data they were unable to obtain. My FOIA requests were denied. Indeed, despite a 1999 law clearly stating that such information should be available to the public, it appears that no data have ever been released under the law. And the price for that secrecy may be paid in American lives.

The use of steroids to treat spinal-cord injuries offers a sobering example. In late March 1990, the NIH announced, with great fanfare, the results of the Second National Acute Spinal Cord Injury Study (NASCIS 2), a 487-person trial that appeared to show that high-dose steroids reduced paralysis caused by acute spinal cord injury. Underscoring the urgency of its results, the NIH issued an unprecedented prepublication press release. This was followed by a "Dear Doctor" letter, which was faxed to emergency departments across the nation, instructing physicians in the correct dosing of steroids for patients with such injuries. Given what was at stake, the NIH's actions appeared to be warranted. Each year, approximately 10,000 people, most of them young and healthy, suffer spinal-cord injuries in car accidents, falls, or shootings. If, as NASCIS 2 suggested, steroids helped prevent paralysis in these cases, it heralded a significant advance in treating people who might otherwise spend their lives on breathing machines and in wheelchairs. The "Dear Doctor" letter ensured that emergency-room physicians would make high-dose steroids the standard of care for victims of spinal-cord injuries.

But not all doctors were as enthusiastic about high-dose steroids as the NIH. Fred H. Geisler, a neurosurgeon with the Illinois Neuro-Spine Institute, had seen not only patients treated with steroids who failed to improve, but also patients who got worse and died--not from their injuries, but from the side effects of the steroids, such as overwhelming infections and gastrointestinal bleeding. Geisler was surprised by the NIH claims, but he knew enough to wait for the published paper so that he could go over the data himself. When the report was published in The New England Journal of Medicine, six weeks after the NIH announcement, it did nothing to allay his doubts. Instead of reporting on all the subjects included in the study, as is customary, the authors wrote up the outcomes on only a subset of patients.

Geisler knew the only way he could confirm his suspicions, or lay them to rest, would be to reanalyze the raw data from the study. But the lead author of NASCIS 2, Michael Bracken of the Yale School of Public Health, refused to release the study data to Geisler and to other critics despite multiple requests. After being contacted by some of these critics in 2003, I filed a formal FOIA request with the NIH for the data. The NIH directed me to Bracken and Yale, saying they did not possess the data. I then requested the data from Bracken and, separately, from Yale. Both denied my requests.

Lacking access to the data underlying the NASCIS 2 claims, most doctors feel obligated to prescribe steroids as the "standard of care." But it's a standard of which many are skeptical. On May 5, 2004, for instance, more than 1,000 neurosurgeons gathered at the annual meeting of the American Association of Neurological Surgeons in Orlando, Florida, to hear a debate between Bracken and Geisler on high-dose steroids. An electronic poll of the audience showed that, prior to the debate, only 21 percent of the neurosurgeons present believed that steroids lead to a significant improvement in outcome (compared with 48 percent who said it didn't improve outcome and 31 percent who responded "don't know"). After the debate, those who said steroids improved outcome dropped from 21 percent to 11 percent, and a mere 6 percent said it ought to be the standard of care. Nonetheless, when asked if they would personally prescribe high-dose steroids for patients with acute spinal cord injuries in the future, 60 of the surgeons present said they would. When asked why, 11 percent said they believed it improved outcome, 31 percent claimed they feared litigation, and 38 percent said there was no better alternative.

The concerns of skeptics like Geisler were recently amplified when the results of another study, known as the CRASH trial, were announced. The study compared patients with serious brain injuries who were treated with steroids with those treated with a placebo. For every 100 patients treated with steroids, three more patients died than did patients treated with the placebo. From these results, Geisler estimates that 5,000 people with spinal-cord injuries have already died from treatment with high-dose steroids--and that stopping steroid treatment could save 300 lives per year in the United States.

Nor is Geisler alone in his concerns. Karim Brohi, a British trauma surgeon at the Royal London Hospital, concurs: "Patients around the world are suffering due to the inappropriate reporting and application of this data," he says. "I believe it is highly questionable that Bracken should be refusing to release the original data given the potential associated morbidity and mortality associated with high-dose steroids." Perhaps the most surprising support for Geisler's views comes from an unexpected source: William Collins, a now-retired Yale neurosurgeon who was Bracken's co-principal investigator on NASCIS 2. Collins says he broke with Bracken and withdrew his name from the third trial in the series in protest because "[Bracken] was always trying to find something that I couldn't find"--i.e., a clinical benefit from steroid treatment.

Nor is this a unique case of taxpayer-funded research being kept hidden. In 2004, an NIH-sponsored study was reported to show that Prozac was effective in treating depressed teenagers. But the NIH and the study authors have refused to release the data in response to FOIA requests--requests, significantly, that were made while Congress and the FDA were holding hearings on the safety of antidepressants. In another NIH study, published in 2003, researchers reported that the brains of children with attention-deficit hyperactivity disorder (ADHD) were smaller than those of children who had not been diagnosed with the disorder. Critics questioned whether the problem might actually be caused by the drugs used to treat ADHD. But, when a researcher asked for the underlying data, his request was denied.

This isn't how it was supposed to be. The Shelby Amendment, passed in 1999, specifically directs federal agencies to "ensure that all data" from federally funded research are "made available to the public through the Freedom of Information Act." The NIH, in its data-sharing guide known as Circular A-110, asserts that data-sharing "is essential ... to improve human health."
Although the NIH officially encourages data-sharing, adherence to the policy is voluntary. It is ultimately left to the individual researcher or research institution to decide whether or not to share their data. As Norka Ruiz-Bravo, NIH Deputy Director for Extramural Research, acknowledged, "Some people share their toys better than others." But the explanation for why so much NIH data are kept under wraps may be more serious than that. Data secrecy is becoming the norm rather than the exception, in an era when researchers--even those who have public funding--are increasingly likely to have commercial interests to protect.

According to a 2003 survey of 171 universities that received NIH grants by the then-General Accounting Office, 91 percent held equity options in the very companies for which they were developing technologies. Some academic institutions receive over $10 million in royalties per year for technologies they have developed. And individual researchers--including some who have refused to release their data in response--have also received funding from sponsoring drug companies. These commercial ties, and the secrecy they spawn, have real consequences for physicians who must rely on research results that may not be entirely disinterested.

It is difficult to know how many dangerous treatments might remain on the market, unchallenged, because of data secrecy. In the case of Prozac for teens, the data withheld by researchers could show that Prozac is not safe for children--an important development, given that it is currently the only anti-depressant approved by the FDA for the treatment of children. In the case of the study showing that the brains of children with ADHD are smaller, it means that stimulant drugs continue to be prescribed even though it is not clear whether brain shrinkage in children with ADHD is caused by the disease--or by the drugs used to treat the disease.

Wondering how widespread the problem of NIH secrecy was, I reviewed the data-sharing exemptions in Circular A-110 and all extramural grants awarded by the NIH in 2005. What I found was that, despite the lofty claims of data-sharing, there are so many exemptions in the guide and the Shelby Amendment that they actually serve to codify data secrecy. For example, only researchers conducting studies that cost more than $500,000 in direct costs annually are required to file a data-sharing plan. Data are also exempt if they are not cited as part of a federal policy or regulation that has the "force and effect of law"--an exclusion that single-handedly eliminates virtually all NIH data.
After reviewing all of the grants awarded by the NIH during 2005 and finding that virtually none of the data would fall under the conditions of mandatory release, I asked the NIH to identify any studies that had been released under the Shelby Amendment. Their answer was surprisingly frank: I was told that, "despite numerous requests" for data since the Shelby Amendment was passed in 1999, "none met the criteria of the regulation."

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