

# Confidential Commercial Information

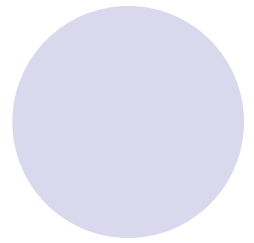
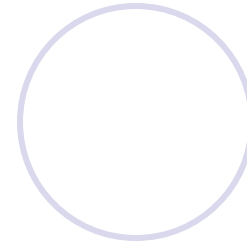
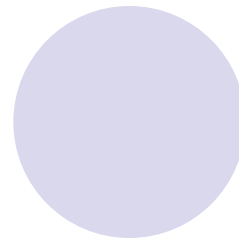
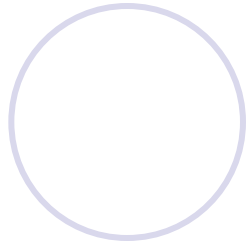
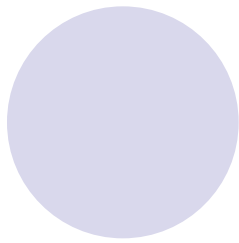
vs.

# Our Right to Know

**Peter Maybarduk**  
**Public Citizen**

[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)

**May 2014**



- \* Confidential Commercial /  
Business Information (CCI / CBI)**
- \* Trade Secrets**

# CCI: Public Interests at Stake

- **Know-how that makes competition possible.**
- **Our right to know: Information about the safety and efficacy of chemicals and pharmaceuticals.**
  - **EMA data disclosure policies**
  - **EU REACH / access to information about regulated chemicals**
  - **Potential for progress on drug data disclosure in U.S.**
  - *Examples: "Contentions that the number of heart attacks was underreported in research about the painkiller Vioxx."*

# Medtronic: Independent Review Shows *Infuse* No Better than Older Treatment

- **“Infuse, a bioengineered material in spinal fusions to treat back pain”**
- **“Company was facing claims that it had published misleading information about the treatment”**
- **Medtronic asked Yale to oversee a detailed review of trial data.**
- **“The two teams that examined the data came to similar conclusions: Infuse appeared to be no better than an older treatment, and may pose added risks.”**

○ **Source: NY Times, [“Breaking the Seal on Drug Research,”](#) Katie Thomas, June 29 2013.**

# Avandia: Failure to Disclose Safety Data

- **Diabetes treatment**
- **Increased risks of heart attack:**
  - **“One study estimated that from 1999 to 2009, more than 47,000 people taking Avandia needlessly suffered a heart attack, stroke or heart failure, or died.”**
- **“Risks became known only after [independent researcher] Dr. Nissen analyzed data ... GSK ... had been forced to post on its Web site as a result of a legal settlement.**
- **Regulatory action suspends Avandia sales in Europe; makes it available only as last resort in U.S. GSK ends Avandia promotion.**
- **GSK promised to end Avandia promotions around the world.**

# Glaxo: Disclosure, After Alleged Malfeasance

- **\$3 billion U.S. DOJ settlement: failing to report Avandia data and publishing misleading data about about Paxil, the antidepressant, in a medical journal, regarding links to the risk of suicide among teenagers.**
- **Glaxo disclosure policy: “after prodding by Dr. Doshi and others, the drug giant GlaxoSmithKline announced that it would share detailed data from all global clinical trials conducted since 2007, a pledge it later expanded to all products dating to 2000.”**

# Data Secrecy Problem: Tamiflu

- **New York Times op-ed, Peter Doshi & Tom Jefferson 2012:**
- **“Tamiflu — data that proved, according to its manufacturer, that the drug reduced the risk of hospitalization, serious complications and transmission — were missing, unpublished and inaccessible to the research community.”**
- **“From what we could tell from the limited clinical data that had been published in medical journals, the country’s most widely used and heavily stockpiled influenza drug appeared no more effective than aspirin.”**
- **“Stockpiling at great taxpayer expense — more than \$1.5 billion. on the basis that it could reduce the duration of flu symptoms by about a day); not for the prevention of transmission.”**

# Data Secrecy Problem: Tamiflu

- **The Guardian, April 10, 2014:**
- **“the [Cochrane Collaboration](#), a global not-for-profit organisation of 14,000 academics, finally obtained all the information. Putting the evidence together, it has found that Tamiflu has little or no impact on complications of [flu](#) infection, such as pneumonia.”**
- **“That is a scandal because the UK government spent £0.5bn stockpiling this drug in the hope that it would help prevent serious side-effects from flu infection.”**
- **“But the bigger scandal is that Roche broke no law by withholding vital information on how well its drug works.”**



# Data Secrecy: U.S. Status Quo

- **New York Times op-ed, Peter Doshi & Tom Jefferson 2012:**
- **“Regulators have never required drug or medical device manufacturers to share their data with independent researchers or academics. They are required to show the information only to the regulators themselves, who treat the data as secret.”**
- **“Use of drugs is often driven by assumptions about drug safety and effectiveness put forth by articles in peer-reviewed journals (sometimes written by doctors affiliated with the drug manufacturers) and clinical practice guidelines that can be entirely inconsistent with the F.D.A.’s assessments.”**
- **“Data secrecy is a disservice to those who volunteer their bodies for clinical trials, and is dangerous to those being asked to swallow approved medicines. Governments need to become better stewards of the scientific process.”**

# Data Secrecy

- For years, researchers have talked about the problem of publication bias, or selectively publishing results of trials. Concern about such bias gathered force in the 1990s and early 2000s, when researchers documented how, time and again, positive results were published while negative ones were not.
- Taken together, studies have shown that results of only about half of clinical trials make their way into medical journals.
- Doshi: Medical profession “relies on hierarchies of trust.”
- “we have partial watchdogs who see part of the full picture.”

# Data Disclosure: U.S. Status Quo

- **No publication requirement – only requirements as to FDA filings**
- **With Investigational New Drug Application, must file trial protocols and summary reports if pursued.**
  - **Companies file summaries of trials to regulators – no patient-level data**
  - **No data if no IND – but this may conceal data about off-label indications companies nonetheless promote**
  - **May conceal data within trials – ex. Analyses run that show unfavorable result**
- **FDA publishes summary of this data, including the Medical Review, published online (sometimes too short notice, and redacted)**
- **Docs obtained from FDA via FOIA sometimes heavily redacted; exemption claims “confidential commercial information and trade secrets.”**

# Data Disclosure: U.S. Status Quo

- **Researchers want to know how FDA came to its conclusions: need more data and more reports; preferably access to raw data**
- **“the F.D.A. — guardian of arguably more trial data than any other entity in the world — appears stuck in the era of data secrecy.”**

# Europe: Progress on Data Disclosure

- **First, researcher access to information, on request**
- **Doshi / Jefferson: “As a result of new freedom of information policies in Europe, the Continent’s version of the F.D.A., the European Medicines Agency, has released 22,000 more pages of Roche’s Tamiflu trial reports. But even this represents an incomplete picture, as the most detailed portions of the reports are not in the European drug regulator’s files.”**

# Europe: Progress on Data Disclosure

- **April 2014: new EU regulation requires that:**
  - the European Medicines Agency set up and run a new, public clinical trials register;
  - a summary of the clinical trial results that is “understandable to a lay person” is published on the register within a year; and that
  - comprehensive, detailed, and structured documents on trial results, called **Clinical Study Reports**, are be made publicly available.

● ***Source:** David Hammerstein in **Open Society Voices**,*

*<http://www.opensocietyfoundations.org/voices/eu-shines-light-shadowy-world-clinical-drug-trial-data>*

# Europe: Progress on Drug Data Disclosure

**One step away: European Parliament approves new clinical trials regulation**

- [Ropes & Gray LLP](#) [Mark Barnes](#), [Eve M. Brunts](#), [David Peloquin](#) and [Shine Chen](#)
- **European Union April 7 2014**
- <http://www.lexology.com/library/detail.aspx?g=dcd459f7-18b2-4f38-bb6d-b3c1eed4b74>
- **requires sponsors who have been approved to hold clinical trials within the EU to post detailed summaries of clinical trial data, including a plain-language summary, within one year of the termination of the clinical trial (e.g., last visit by the last subject or as otherwise defined in the protocol). All summaries will be centralized on a publicly accessible, free and searchable database of all approved clinical trial data relating to medicinal products.**
- **On the same database, within 30 days of the marketing application's authorization, rejection or withdrawal, sponsors will be required to post full clinical study reports that were submitted to EMA in support of the marketing application. Failure to post the summaries or final clinical study reports will result in fines.**

# AmCham EU: T-TIP Should Favor Data Secrecy

**AmCham EU: Protect confidential commercial information ... there is concern that the current and proposed policies of the European Medicines Agency (EMA) regarding marketing application data disclosure jeopardise the privacy of patients, integrity of regulatory systems, and incentives to invest in research in the biopharmaceutical sector that benefits patients.**

- **Failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in TRIPS.**
- **The U.S. should raise trade-related concerns with these EMA policies in the context of the TTIP discussions .. and respect intellectual property rights, including confidential commercial information.**
- [http://www.amchameu.eu/DesktopModules/Bring2mind/DMX/Download.aspx?TabId=165&Command=Core\\_Download&EntryId=9826&PortalId=0&TabId=165](http://www.amchameu.eu/DesktopModules/Bring2mind/DMX/Download.aspx?TabId=165&Command=Core_Download&EntryId=9826&PortalId=0&TabId=165)



# BIO Comments on T-TIP and CCI

- <http://www.bio.org/sites/default/files/BIO%20TTIP%20submission%20May%202013%20final%205%2017%202013.pdf>. at 10:
- **“BIO urges U.S. negotiators to explore provisions to ensure the non-disclosure of all commercial confidential information (CCI) submitted to regulatory authorities in connection with regulatory approval of bio-pharmaceutical products. This is particularly important in light of recent EMA actions that would lead to the public disclosure of non-clinical and clinical study reports containing CCI. It is imperative that both the U.S. and the EU maintain uniform protection of patient privacy and CCI and trade secrets submitted in marketing approval applications. The EMA’s current and proposed data disclosure policies are not consistent with these principles.”**

# PhRMA

- <http://www.regulations.gov/contentStreamer?objectId=09000064812d9cad&disposition=attachment&contentType=pdf> at 12

●  
**“The EMA’s current practices, in addition to its proposed policies to proactively disclose companies’ non-public data ... risk damaging public health and patient welfare ...”**

**“Further, failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU’s treaty obligations contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).” [cites Art 39.3]**

**“For these reasons, PhRMA and its members urge the U.S. Government to engage with the EU in every available venue to resolve this issue.”**

# EU Regs Meet TRIPS Requirements

- ***TRIPS Article 39***
- **1. *In the course of ensuring effective protection against unfair competition ... Members shall protect ... data submitted to governments or governmental agencies in accordance with paragraph 3.***
- **3. *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data ...***
- **Members shall protect such data against disclosure,**
- **except where necessary to protect the public,**
- **or unless steps are taken to ensure that the data are protected against unfair commercial use.**

## **Analysis:**

- **Disclosure of test data clearly is necessary to protect the public, and**
- **The requirements apply to trials, not commercial information.**

# Evaluating Arguments for Data Secrecy in T-TIP

- **Trial data aren't trade secrets.**
- **Patient privacy not compromised**
  - **EU requires summaries, not patient-level data**
- **Trade negotiation not competent to address merits**
  - **(health need, privacy or legality)**
- **Progress on drug data disclosure is very important; we should support EU progress and pursue the same in US**

# **Public Citizen: Pharma Industry is Biggest Defrauder of Fed Government under False Claims Act, 2010**

- **Pharmaceutical cases accounted for at least 25% of False Claims Act payouts over the past decade, compared with 11% by the defense industry**
  - **More than one-half of the industry's fines were paid by four companies – GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough**
  - **“Desperate to maintain their high margin of profit in the face of a dwindling number of important new drugs, these figures show that the industry has engaged in such activities as dangerous, illegal promotion for unapproved uses of drugs and deliberately overcharging vital government health programs, such as Medicare and Medicaid.”**
- Sidney Wolfe, director of the Health Research Group, Public Citizen**

# **The Guardian: Big pharma mobilising patients in battle over drugs trials data**

**Leaked memo from industry bodies reveals strategy to combat calls by regulators to force companies to publish results**

*Ian Sample, science correspondent, The Guardian, Sunday 21 July 2013*

- **“The pharmaceutical industry has “mobilised” an army of patient groups to lobby against plans to force companies to publish secret documents on drugs trials.”**



**“According to the Center for Responsive Politics, the pharmaceutical and health-care-product industries, combined with [other health-related] organizations, have spent \$5.36 billion since 1998 on lobbying in Washington. That dwarfs the \$1.53 billion spent by the defense and aerospace industries and the \$1.3 billion spent by oil and gas interests over the same period. That’s right: the health-care-industrial complex spends more than three times what the military-industrial complex spends in Washington.”**

**-Steven Brill, *Bitter Pill: Why Medical Bills are Killing Us***

# Confidential Commercial Information

vs.

# Our Right to Know

**Peter Maybarduk**  
**Public Citizen**

[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)

**May 2014**