

The New Transparency: What Will it Mean for the Practice of Medicine?

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David Rothman is serving as a consultant and expert witness for the office of the Attorney General of the State of Texas in its litigation against Johnson & Johnson related to Risperidone.

THE THEORY OF TRANSPARENCY

“Sunlight is said to be the best of disinfectants; electric light is the most efficient policeman.”
(Justice Louis Brandeis)



- People behave best when closely watched
- The concept first took hold in government, went on to affect industry, then other social institutions, and now, finally, is beginning to take hold in medicine.

TRANSPARENCY IN MEDICINE

OUR SUBJECTS TODAY:

- A brief analysis of the history of transparency
- How transparency spread to medicine
- What are its implications for physicians and patients?

THE FREEDOM OF INFORMATION ACT (FOIA)

- The foundation stone of government transparency.
- Lyndon Johnson signed it into law on July 4, 1966, grudgingly and with no formal signing ceremony.
- He himself had numerous objections as did many federal agencies. They feared that:
 - Republicans would use it to their political advantage
 - National security would be jeopardized
 - Journalists would rummage through files in search of dirt
 - Citizen requests would overwhelm the bureaucracy



TRANSPARENCY

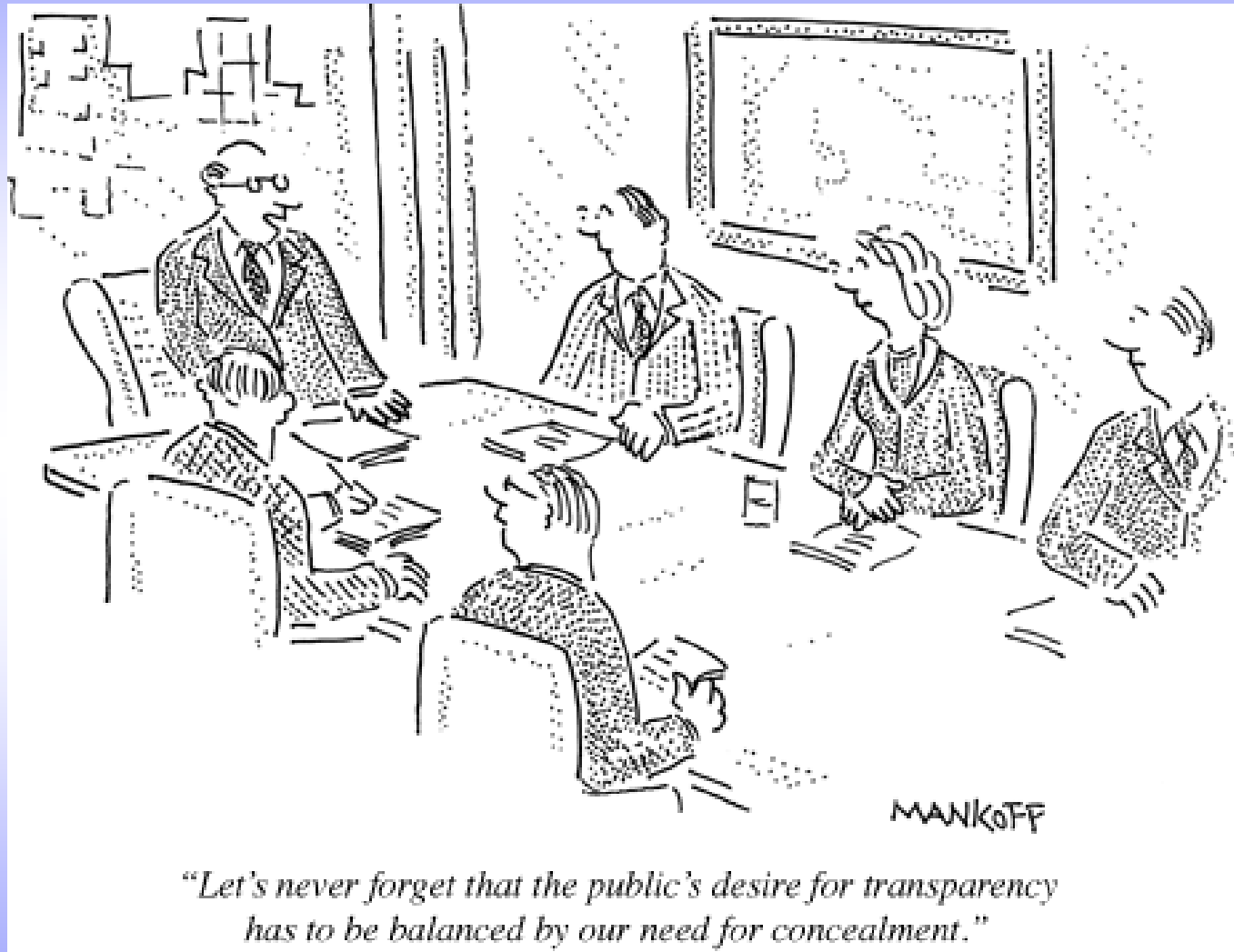
- Transparency is contagious. Following on FOIA, federal and state governments enacted **sunshine laws** to open up administrative meetings once held behind closed doors.
- Transparency is controversial: Wikileaks.
- Transparency is global. Some 90 countries around the world, including China, have FOIA-type legislation.

TRANSPARENCY

Transparency produces data as well as information.

- Automobile manufacturers must put stickers on the windows of new cars detailing roll-over test results.
- Food manufacturers and chain restaurants must report fat, calorie, sugar, and salt content of their products.
- Not-for-profit organizations must make public salaries of their chief executives and five highest paid earners.
- Public companies must provide profit, loss, and expenditure data and describe fully potential risks and returns when they float new stocks.

THE LIMITS OF TRANSPARENCY



THE LIMITS OF TRANSPARENCY (Cont.)

From the Would-Be Consumers of the Information:

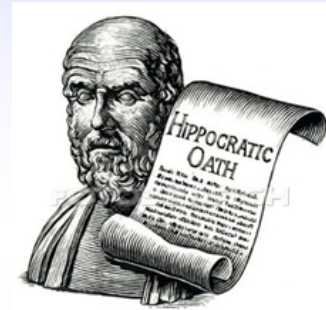
- Very few people read/understand the food labels.
- Even fewer people read/understand the fine print in corporate reports.
- And even fewer people than that consult Guidestar to learn about salaries.

Nutrition Facts	
Serving Size ½ cup (114g)	
Servings Per Container 4	
Amount Per Serving	
Calories 90	Calories from Fat 30
% Daily Value*	
Total Fat 3g	5%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 300mg	13%
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	
Vitamin A 80%	Vitamin C 60%
Calcium 4%	Iron 4%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

BRINGING TRANSPARENCY TO MEDICINE

A more complicated and problematic assignment.
There are important competing principles:

- **Physician confidentiality**-- going back to the Hippocratic Oath.
- **Patient privacy**-- enshrined in the 1996 Health Insurance Portability and Accountability Act (HIPAA).



BRINGING TRANSPARENCY TO MEDICINE

And yet, changes have come to medicine as well.

The Medical Chart:

- Once considered the exclusive preserve of health care providers. But as the concept of patient autonomy took hold in the 1980s, patients and their families increasingly, and successfully, demanded to see the chart. Eventually, HIPAA guaranteed their right to do so.

Medical Outcomes

- New York was among the first states to require hospitals to release the results of coronary artery by-pass procedures by institutions and by surgeons.

OUTCOMES BY SURGEON

	Isolated CABG					95% CI for RAMR	Isolated CABG, or Valve or Valve/CABG	
	Cases	No of Deaths	OMR	EMR	RAMR		Cases	RAMR
NY Methodist Hospital								
#Lee L Y	150	3	2.00	2.22	1.77	(0.36, 5.16)	205	2.54
#Tortolani A	217	1	0.46	2.00	0.45	(0.01, 2.51)	291	2.50
All Others	10	0	0.00	1.14	0.00	(0.00,62.82)	10	0.00
Total	377	4	1.06	2.07	1.01	(0.27, 2.58)	506	2.50
NYP- Columbia Presby.								
Argenziano M	105	4	3.81	1.62	4.61	(1.24,11.81)	312	3.95
#Chen J M	(. , .)	1	0.00
##D Alessandro D A	2	0	0.00	1.72	0.00	(0.00,100.0)	3	0.00
Mosca R S	1	0	0.00	0.38	0.00	(0.00,100.0)	5	30.48
Naka Y	232	8	3.45	1.75	3.87	(1.67, 7.63)	446	4.66
Oz M	252	2	0.79	1.23	1.26	(0.14, 4.55)	715	3.83
#Quaegebeur J	(. , .)	10	0.00
Smith C	255	5	1.96	1.05	3.65	(1.18, 8.51)	777	3.15
Stewart A S	263	7	2.66	2.23	2.34	(0.94, 4.81)	528	3.74
All Others	36	2	5.56	2.12	5.13	(0.58,18.51)	98	6.59
Total	1146	28	2.44	1.59	3.01 *	(2.00, 4.35)	2895	3.95 *

Other Medical Outcomes

- Rates of in-patient infections
- Rates of medical error
- Rates of patient falls

WHO USES THE DATA?

An Open question.

- **Named Individuals do**
- **Named Institutions do**
- **Very doubtful if patients/consumers do**

BRINGING TRANSPARENCY TO MEDICINE: FINANCIAL DATA ON PHYSICIANS AND COMPANIES

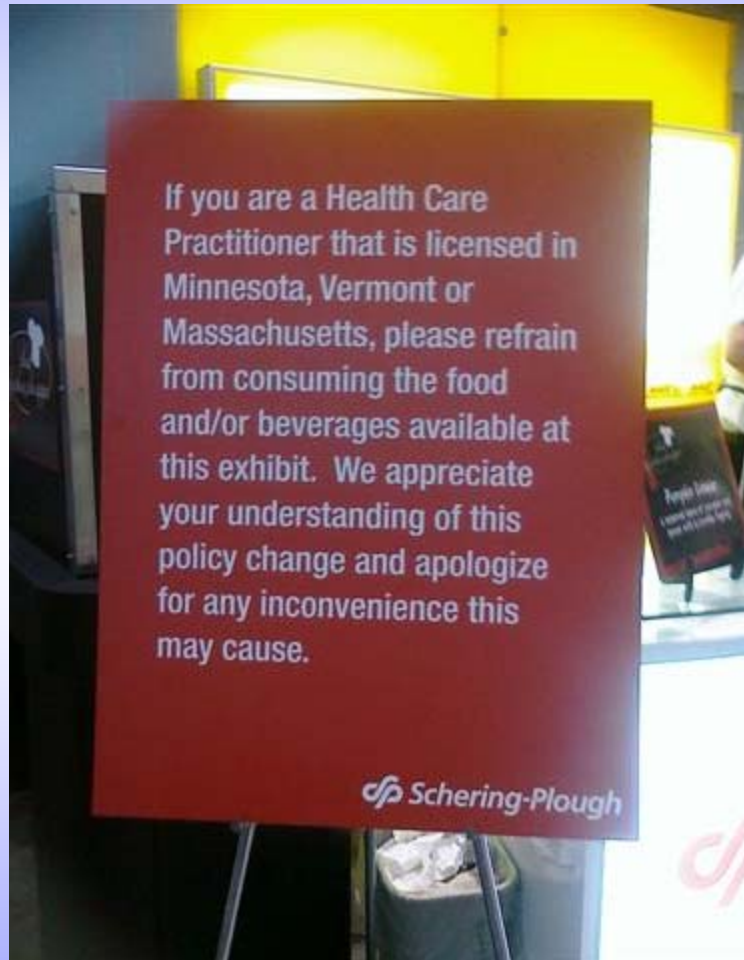
Over the past five years, a revolution has occurred in the disclosure of doctor/company financial arrangements.

BRINGING TRANSPARENCY TO MEDICINE: FINANCIAL DATA ON PHYSICIANS AND COMPANIES

Legislative Initiatives: State and Federal

- Six states now require drug companies to report gifts and payments to physicians
- Many others are considering similar bills

STATE INITIATIVES



FEDERAL INITIATIVE



Physician Payments Sunshine Act of 2009:

To amend title XI of the Social Security Act to **provide for transparency in the relationship between physicians and manufacturers** of drugs, devices, biological, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

INDUSTRY DISCLOSURE

- Over the past few years, 14 companies began posting payments to health professionals and organizations on their websites.
- As part of settlements to resolve prosecutions, the device companies Biomet, DePuy, Smith & Nephew, Stryker, and Zimmer agreed to disclose their payments to “consultants.”
- Pharmaceutical companies have also agreed to disclose:

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Dollars for Docs

What Drug Companies are Paying Your Doctor

Top Earners

Story: [Who's on Pharma's Top-Paid List?](#)

In **October 2010**, ProPublica identified **384** healthcare providers who earned more than **\$100,000** total from one or more of the seven companies that have disclosed payments in 2009 and early 2010. We matched the payee records with licensed doctors and registered nurses in the states listed. When a match could not be found, for example when a recipient was a pharmacist, we used other sources to confirm their identities.

The payments are listed as we compiled them in October 2010 and so the displayed total may not be up-to-date. Do a [search](#) to find the recipient's latest payments.

See more details about the [compilation of this list](#).

If you are a listed practitioner and believe you do not belong in this database, please contact us at ornstein.weber@propublica.org.

Name	State	Certification	Payments
Firhaad Ismail	Nev.	Internal Medicine; Endocrinology and Metabolism	GSK \$209,400 Eli Lilly \$81,608 Merck \$12,550 \$303,558
Stephen H. Landy	Tenn.	Neurology	GSK \$168,800 Cephalon \$131,300 Merck \$2,025 \$302,125
Samuel Dagogo-Jack	Tenn.	Internal Medicine; Endocrinology, Diabetes and Metabolism	GSK \$151,700 Eli Lilly \$98,987 Merck \$6,325 \$257,012

IMPLICATIONS OF THE NEW TRANSPARENCY

- For the first time, full and accurate data on company payments to physicians and health care organizations, independent of individual disclosures.
- No one has disputed the accuracy of company figures as reported on websites or to states.
- There is confusion about terms and 1099 forms.
- What you take/receive is now public information.

IMPLICATIONS OF THE NEW TRANSPARENCY

Will Transparency Change Practices?

Perhaps Not:

- Very few resignations from Speakers' Bureaus as companies post payouts
- Suggestions that seeing colleagues' compensation will drive up your own demands
- Consumers do not use databases very well
- Consulting the databases, which are not now consolidated, is cumbersome

IMPLICATIONS OF THE NEW TRANSPARENCY

Will Transparency Change Practices?

More likely Yes: why trust if you can verify?

- Academic Medical Center use
- Professional Medical Associations use
- Journal use
- Student use
- FDA/NIH use
- Media use
- Educated consumer use

IMPLICATIONS OF THE NEW TRANSPARENCY

Transparency will change practice.

Disclosure will not be a license, but will prompt disqualification.

Data that gifts, consultancies, honoraria, and other payments bias the recipient is overwhelming.

Therefore, appointments to lecture, join formulary committees, serve on FDA advisory committees or NIH study groups, are likely to be affected.

A possible emergence of a two-track system:

- The **Entrepreneur** for whom transparency provides public recognition of financial success.
- The **Professional** who accepts no personal industry funding, so as to pursue leadership positions within the profession.