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Off-Label Communications and the Constitution: Will FDA Finally Change its Policies?

Presentation to the Pharmaceutical Compliance Forum

Paul E. Kalb, M.D.

November 4, 2014

Changing Healthcare and Legal Environments

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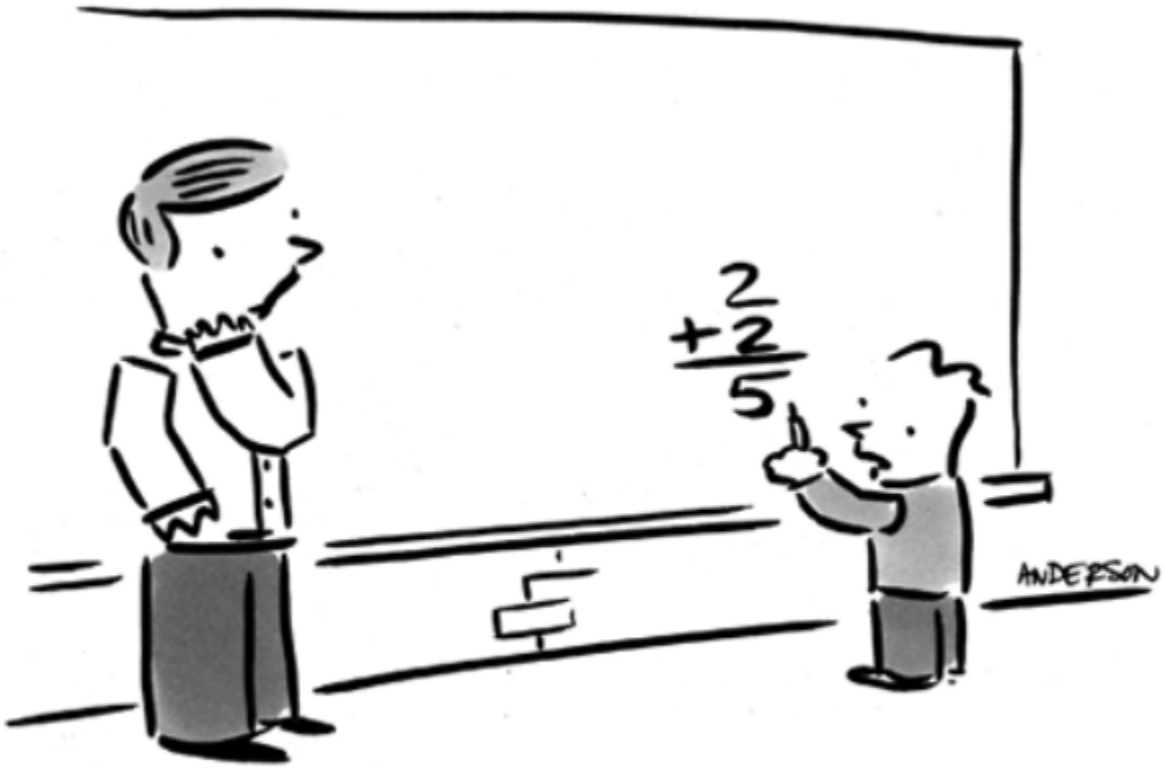

"I prefer to think of it as added value."

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National Quality Strategy – Key Component of ACA

2010

The Triple Aim and Six Quality Priorities Are Driving New Accountabilities

http://www.ahrq.gov/workingforquality/index.html

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The New York Times http://nyti.ms/1iv1lmQ

BUSINESS DAY | NYT NOW

Cost of Treatment May Influence Doctors

By ANDREW POLLACK APRIL 17, 2014

Saying they can no longer ignore the rising prices of health care, some of the most influential medical groups in the nation are recommending that doctors weigh the costs, not just the effectiveness of treatments, as they make decisions about patient care.

The shift, little noticed outside the medical establishment but already controversial inside it, suggests that doctors are starting to redefine their roles, from being concerned exclusively about individual patients to exerting influence on how health care dollars are spent.

"We understand that we doctors should be and are stewards of the larger society as well as of the patient in our examination room," said Dr. Lowell E. Schnipper, the chairman of a task force on value in cancer care at the American Society of Clinical Oncology.

In practical terms, new guidelines being developed by the medical groups could result in doctors choosing one drug over another for cost reasons or even deciding that a particular treatment — at the end of life, for example — is too expensive. In the extreme, some critics have said that making treatment decisions based on cost is a form of rationing.

Traditionally, guidelines have heavily influenced the practice of medicine, and the latest ones are expected to make doctors more conscious of the economic consequences of their decisions — even though there is no obligation to follow them. Medical society guidelines are also used by insurance companies to help determine reimbursement policies.

The society of oncologists, alarmed by the escalating prices of cancer medicines, is developing a scorecard to evaluate drugs based on their cost and

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The society of oncologists, alarmed by the escalating prices of cancer medicines, is developing a scorecard to evaluate drugs based on their cost and value, as well as their efficacy and side effects. It is expected to be ready by this fall.

And the American College of Cardiology and the American Heart Association recently announced that they would begin to use cost data to rate the value of treatments in their joint clinical practice guidelines and performance standards.

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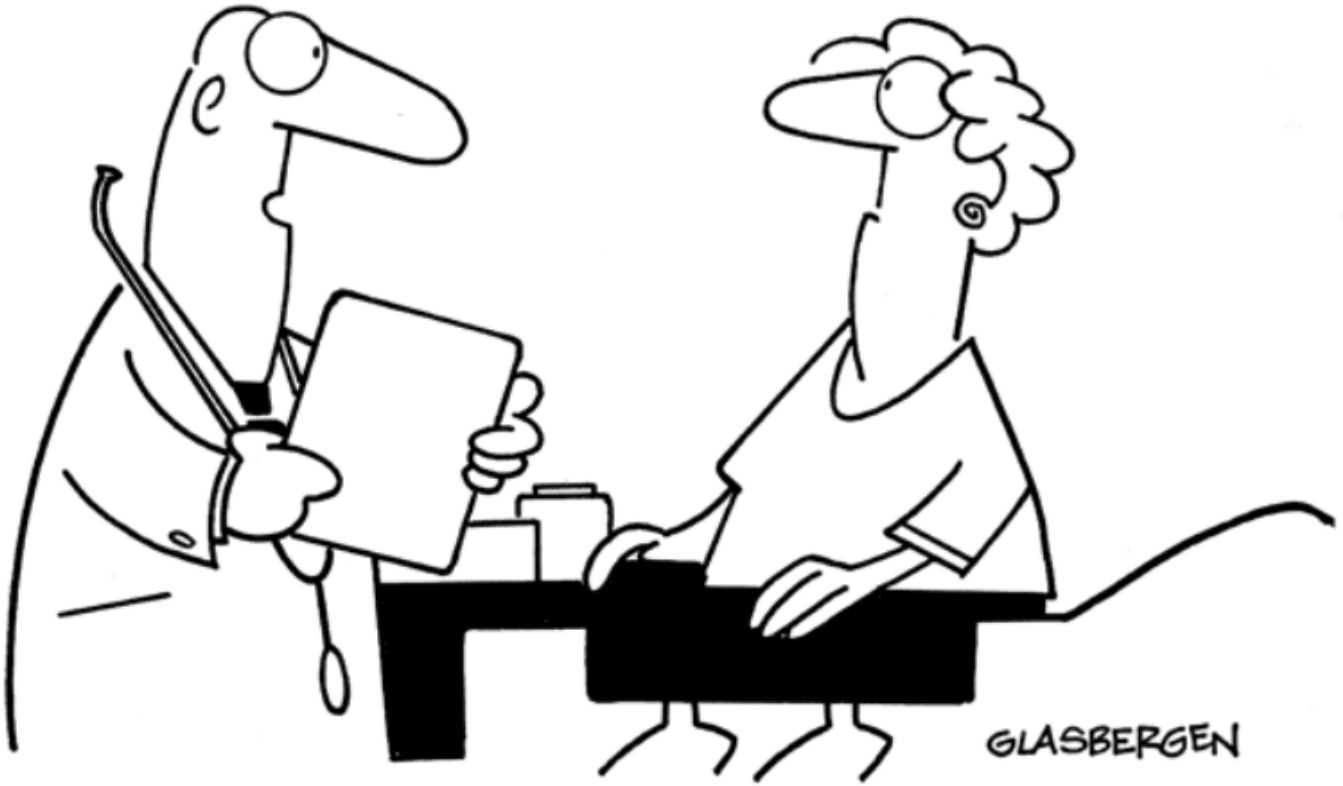

**"I looked up your symptoms on Google.
If you want a second opinion, I can check Yahoo."**

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"Before I couldn't keep him off the couch.
Now a new problem has arisen."

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"Speech in aid of pharmaceutical marketing…is a form of expression protected by the Free Speech Clause of the First Amendment."

"Vermont's law thus has the effect of preventing detailers—and only detailers—from communication with physicians in an effective and informative manner…It follows that heightened judicial scrutiny is warranted."

"That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers."

Free flow of commercial speech "has great relevance in the fields of medicine and public health, where information can save lives."

– Sorrell v. IMS Health, 131 S. Ct. 857 (2011)

"[R]egulated parties should know what is required of them so they may act accordingly…when speech is involved, rigorous adherence to [this] requirement is necessary to ensure that ambiguity does not chill protected speech."

– FCC v. Fox Television Stations, Inc., 132 S. Ct. 2307 (2012)

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"The FDA's contention that neither it nor this Court has the authority to second-guess Congress, even if the congressional mandate violates the First Amendment, is an oh-too-convenient dodge…Congress must pass laws, and the FDA must implement final rules, that are consistent with the requirements of the Constitution."

- R.J. Reynolds Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012)

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"[U]nder the principle of constitutional avoidance, we construe the FDCA as not criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns."

"[T]he government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."

"[W]e conclude that the government's construction of the FDCA's misbranding provisions imposes content- and speaker-based restrictions on speech subject to heightened scrutiny. Second, we conclude the government cannot justify a criminal prohibition of off-label promotion even under Central Hudson's less rigorous intermediate test."

– United States v. Caronia, 703 F.3d 149 (2d Cir. 2012)

MIWG vs FDA

MIWG vs. FDA

"The lack of clarity and vagueness surrounding the contours of permissible manufacturer speech has significant consequences to manufacturers, the government, physicians, and patients."

FDA should therefore promulgate regulations to provide clarity with respect to 4 specific safe harbors: (1) Scientific exchange, (2) Responses to unsolicited requests, (3) Dissemination of clinical practice guidelines, and (4) Interactions with payers, formulary committees, and similar entities.

– Citizen Petition #1 (July 2011) filed by 7 members of the MIWG

MIWG vs. FDA

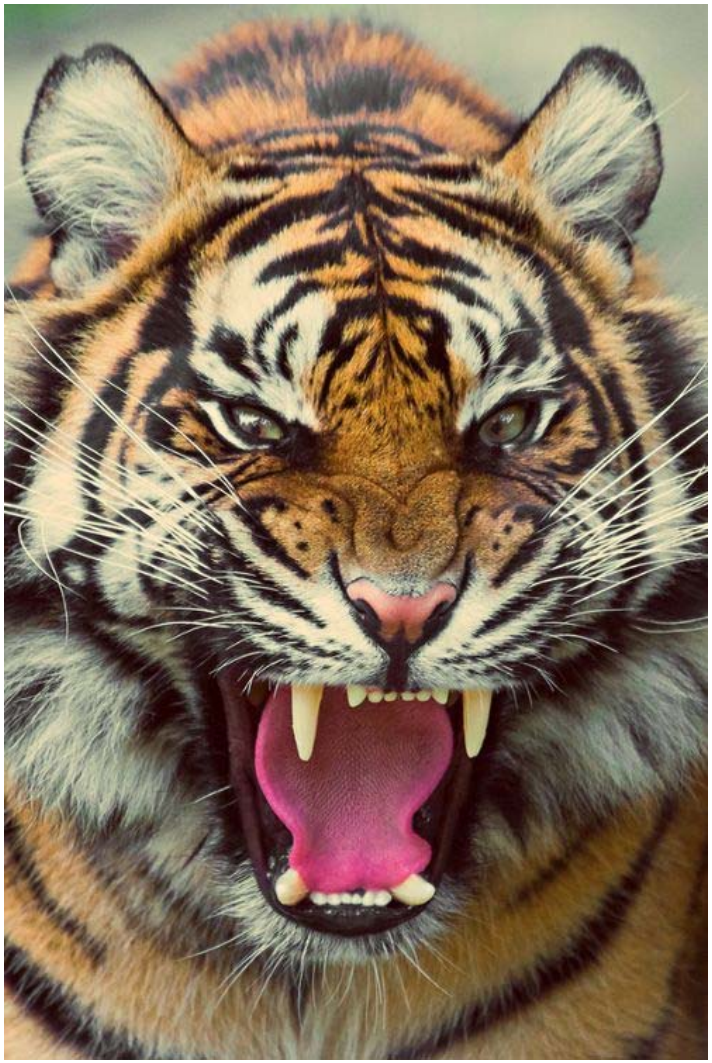
"FDA should take the opportunity provided by important developments in the case law to revise its approach to the regulation of manufacturer speech. In so doing, FDA must recognize that is cannot and should not regulate scientific exchange—because of limitations imposed by the First Amendment and by the statue, and in recognition of the need for the unfettered flow of information and scientific developments, in medicine as in other areas of scientific endeavor."

– Comments of the Medical Information Working Group on Scientific Exchange Docket (March 27, 2012)

FDA should "comprehensively review, and modify as necessary in view of constitutional and statutory limitations, the regulatory regime governing manufacturer communications to protect and promote the public health."

– Citizen Petition #2 (September 2013)

FDA Responses



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FDA Responses

Caronia could undermine the Drug Amendments of 1962, which "would be a nightmare"

"What is worth talking about is what the consequences would be if people could promote uses that they hadn't established, hadn't bothered to get through the system," Temple stated. "I'm horrified by that."

– Robert Temple, Deputy Director of Clinical Science, CDER
in "Off-Label Rulings Potential Fallout is 'Terrifying,'" The Pink Sheet, Dec. 17, 2012

FDA Responses

"The decision does not strike down any provision of the FD&C Act or its implementing regulations, nor does it find a conflict between the Act's misbranding provisions and the First Amendment or call into question the validity of the Act's drug approval framework."

– Tom Abrams, CBI Pharmaceutical Compliance Congress, January 24, 2013

The First Amendment does not affect False Claims liability, which is premised on the submission of a false claim, and not on speech qua speech.

– Statement of Interest in United States ex rel. Matthew Cestra v. Cephalon, Inc. (S.D.N.Y. Nov. 7, 2013)

FDA's Changing Views

FDA's Changing Views

FDA is "carefully evaluation [its] policies in light of court decisions on First Amendment issues."

- Janet Woodcock, 2014 FDLI Conference

FDA "recognize[s] the changing First Amendment jurisprudence [and is] taking the First Amendment concerns [it has] heard very seriously."

- Leslie Kux, 2014 FDLI Conference

"Industry challenges…are driving a new commitment at the highest levels of the agency…to realign FDA's regulatory posture in this area."

- Elizabeth Dickinson, 2014 FDLI Conference

FDA's Changing Views

"The Agency has recognized – and continues to recognize – that there can be utility in the dissemination of truthful and non-misleading scientific or medical information regarding off-label uses under appropriate circumstances."

FDA is "granting [MIWG's] request for a review of FDA's regulations, guidance, and policies, and for more clarity on truthful, non-misleading scientific communications and activities related to investigational new drugs and investigational devices and off-label uses of marketed drugs and devices. These tasks are part of FDA's more comprehensive review of its regulations and guidance documents in an effort to harmonize the goal of protecting the public health with First Amendment interests."

– Leslie Kux, Response to MIWG Petition (June 2, 2014)

What Will Not Happen?

The Drug Approval Process Will Not Crumble

Brick house indeed... Just wait and see my friend!...

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What Can We Hope For?
More Space for Scientific Exchange

On-Label | Scientific Exchange | Off-Label

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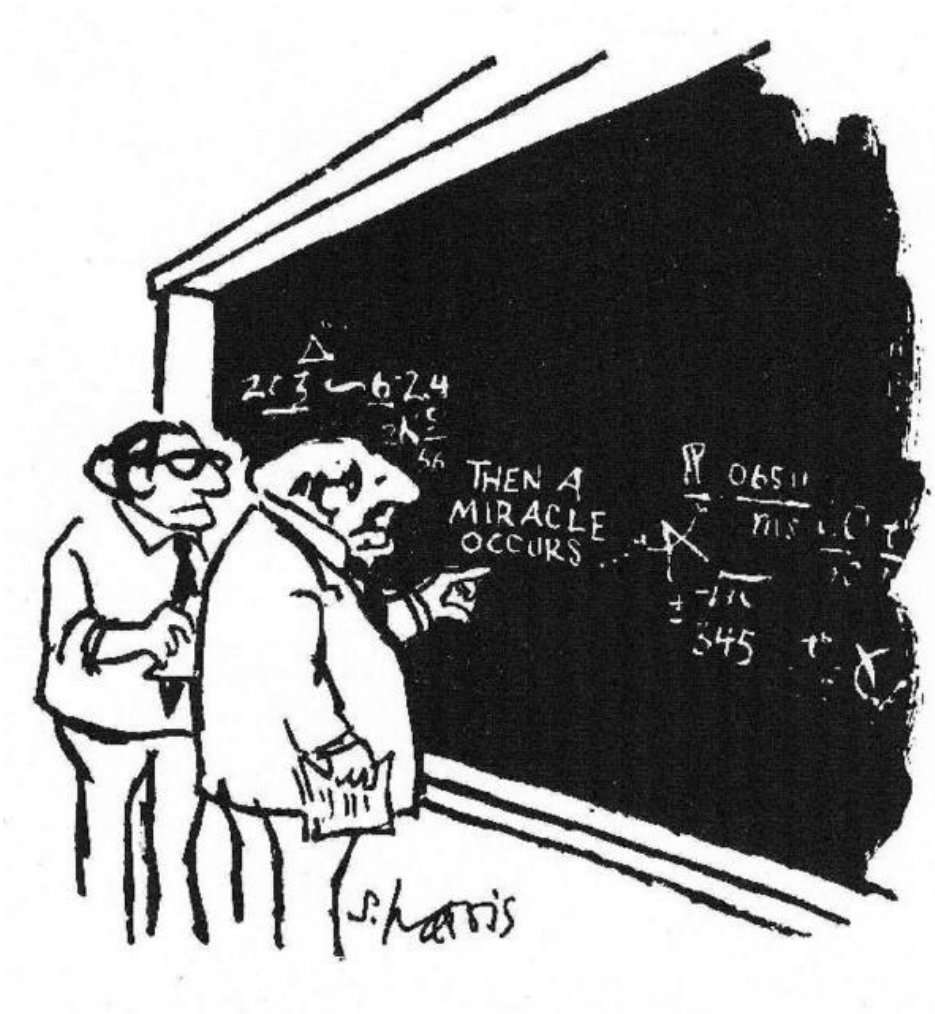
What Can We Hope For?
More Space for Scientific Exchange



"I think you should be more explicit here in step two."

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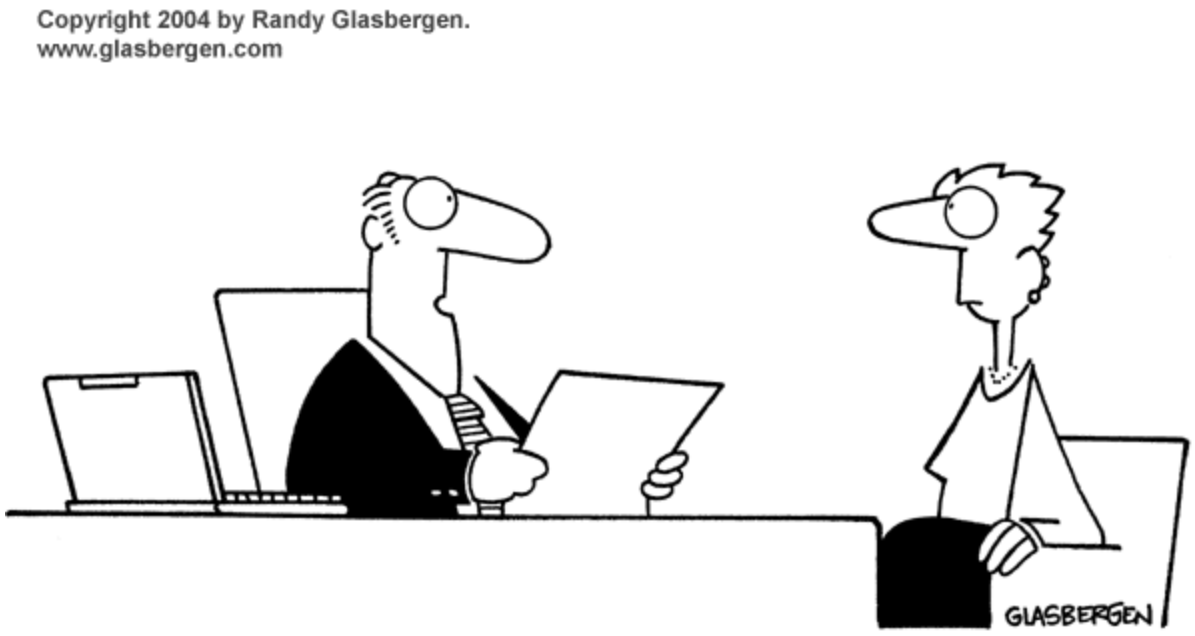
What Can We Hope For?

Better Manufacturer-Payor Communications → Better Outcomes



"We can contain health insurance costs if you're willing to let your coworkers diagnose you with information they find on the Internet."

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What Can We Hope For?

Better Manufacturer-Payor Communications → Better Outcomes

"The insurance company will pay for my transplant, but only if the doctor uses an artichoke heart."

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What Can We Hope For?

Better Manufacturer-Payor Communications → Better Outcomes

"I was very ill and my HMO wouldn't pay for human parts."

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