

amplify

BIO *con brio!*

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At the recent BIO conference I had the pleasure of chairing a panel entitled, “*Advertising or Freedom of Expression? Cross-Border Communications and the New World Order.*” And a high-powered panel it was. I was joined by Jack Bierig (Sidley Austin), Marie Kennedy (Baxter) and Ray Kerins (Pfizer).

An audio recording of the panel can be found on the BIO site (www.bio.org).

Here are my remarks:

If health care is a “right,” then is access to information about health care also a right?

Well, where you stand depends on where you sit and, for biopharmaceutical companies, it determines how you act.

And nowhere at BIO 2010 will you find a more lively, engaging, and expert panel to debate this timely and crucial issue than right here and right now. Welcome to BIO *con brio*.

What’s going on in the U.S.? Does the First Amendment still count? What’s going on in the EU? Does “information to patients” really mean anything? In the complex and hyper-bureaucratic world of Brussels, is reform going anywhere beyond just words?

And when it comes to health care communications, wither social media on either side of the pond?

Let’s start with a look at what’s going on in Europe.

The situation “over there” can be summed up by James Copping of the European Commission’s Enterprise & Industry Directorate. According to Mr. Copping:

“We have an unsustainable mix of regulations, and the legislation on advertising was largely drafted in the 1980s, before the Internet became a daily feature of many people’s lives.”

In 2006 I challenged Mr. Copping at a debate sponsored by the Centre for the New Europe. He said, “We must find new ways to regulate health-care information to patients.” I then suggested that a better way to frame that statement would be to say that “the EU needs to find a better way to facilitate health-care information to patients.” To which Mr. Copping replied, “Yes, that’s right.”

WHAT’S NEXT?

Well, that was then and this is now. But before we see what’s sprouting in Brussels pursuant to the shifting of ITP authority from Enterprise & Industry to DG SANCO, let’s turn our attention northwards to Denmark for a disturbing twist and a reminder that “free speech” means something very different in Europe than it does here in the U.S.

In 2003, Danish journalist Frede Damgaard published information on his website about Hyben Total, a treatment for a wide range of conditions—including gout, kidney and bladder disorders, sciatica, diarrhea and diabetes. The Danish national regulator in 1999 refused it a marketing authorization. It is still sold as a medicine in Sweden and Norway.

Mr. Damgaard’s positive description of Hyben Total’s effects on the symptoms of gout and arthritis led to his being prosecuted in the Danish courts on the grounds that it constituted advertising of a medicinal product whose sale was not authorized in Denmark – and the Danish court specifically cited Article 86 of European Union Directive 2001/83/EC, which defines the concept of medicines advertising.

(This is disturbing on a number of levels, not the least of which is the Danish court’s almost complete dissonance with the Danish Prime Minister Anders Fogh Rasmussen’s statements – in the wake of the “cartoon scandal” of 2005 that, “Freedom of Speech is absolute. It is not negotiable.”)

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Mr. Damgaard appealed to the European Court of Justice, claiming that his discussion of Hyben Total could not be held to constitute advertising since he had no interest in selling the product, and also that the court decision contravened European Union protections of freedom of expression. And the ECJ agreed.

VERDICT OR VAGUENESS?

According to the opinion handed down by the ECJ Advocate General, “a lack of connection between the author of the information and the sellers or manufacturers of the medicinal product and the non-commercial or non-industrial nature of the activity of that independent third party may...be strong indications that a message does not have promotional content.”

The advocate general added that this was not an isolated case; similar situations had arisen recently over statements about melatonin in Spain, and in the Czech Republic, over a collection of media features titled “Yesterday Viagra, today Cialis.”

The advocate general concluded that it’s up to individual EU member states “to ensure the correct balance between, on the one hand, the objectives of protecting health and promoting the rational use of medicinal products and, on the other, the right of the party concerned to freedom of expression, taking into account the special protection afforded to the party concerned, if it is established that he is a journalist.”

But how do you “establish” who is and who is not a “journalist?”

Not a complete victory for the Fourth Estate and uncomfortable silence from the court about free speech for non-journalists. What about free speech for physicians and patients and, yes – even biopharmaceutical companies?

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AND SO WE RETURN TO BRUSSELS.

Recent reports have spoken about “renewed optimism” that the EU’s proposed legislation on allowing drug makers to provide information to patients on prescription-only medicines will again start moving through its treacle-like legislative process. The latest thinking, however, is strongly focused on the rights of patients to receive such information, rather than industry’s right to disseminate it.

That’s an interesting and important finesse – the rights of a patient to the information but no “right” for industry *to provide it*. Hmmm.

Suggested amendments to the most current consultation document emerged on March 10th from M.E.P. Christofer Fjellner, who’s reviewing the proposed legislation for the EU parliament’s Committee on the Environment, Public Health and Food Safety.

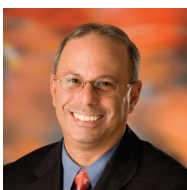
The environment committee will vote on the patient information proposals this June. After that a plenary vote of all European Members of Parliament will be held in September. It will then go to the Council of the EU for further consideration. Process as proxy for action. As Julian Morris of the London-based International Policy Network quipped, “Europe is running out of failed alternatives.”

The battle lines are drawn. Brussels moves in mysterious ways and “consensus” is a very un-American concept.

EU president Herman Van Rompuy is often referred to as “Haiku Herman” frequently ending his speeches with a composition of this own. And so, in keeping with the transatlantic nature of the topic at hand, let me do the same:

**Health information.
When will Brussels move forward?
We watch and await.**

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