Shamoo and Schwartz (2008) argue that federal or state regulation of all research protocols is needed for the protection of human subjects. And yet, their recommendations do not address the amount of information referencing clinical trials that implicitly endorses a therapeutic misconception. That is, this information implies that clinical trials are beneficial or therapeutic for research subjects. As an early encounter with clinical trials, this information may crystallize for potential subjects a mistaken perspective of what clinical trials are meant to do. Accordingly, this information will limit, if not undermine, the value of the kinds of regulation Shamoo and Schwartz recommend. Nonetheless, it is far from clear that there is a tractable and useful way to address the role of this information in molding patient/research subject understanding of clinical trials.

**Two Examples**

For the last several months, a radio ad for the brand Novartis that mentions a clinical trial has aired in New York City. I requested the script of this advertisement, and they directed me to thinkwhatspossible.com. There I found the following text:

“Seven years ago, LaDonna was dying from cancer. Doctors gave her just months to live. Then, she heard about a Novartis clinical trial and enrolled in it — and she’s been in remission ever since, welcoming two new grandchildren into her life. A patient will stop at nothing to fight cancer. This same determination drives
research at Novartis. We are committed to developing targeted medicines, and when we find one that works, we don’t stop there.” Accessed September 26, 2008.

Even though every single word of this advertisement may be true, the story could, and perhaps should, include the following details: 1) the clinical trial held the prospect of no benefit for LaDonna and it is only luck that led to her recovery and current levels of health (after all it could have been a clinical trial for a drug that didn't work), and 2) Novartis is likely making profits from the information they gathered from her participation in the trial.

At the website for CenterWatch Clinical Trials Listing Service, there is a great deal of information about the structure of clinical trials, a list of questions for patients to ask their physicians about clinical trials, and the following paragraph:

"People participate in clinical research for a variety of reasons. People who volunteer for phase II and phase III trials can gain access to promising drugs long before these compounds are approved for the marketplace. They typically will get excellent care from the physicians during the course of the study. This care also may be free." http://www.centerwatch.com/patient/backgrnd.html. Accessed September 26, 2008.

Again, even though every word of this paragraph is true, it could also be written as follows:
"People participate in clinical research for a variety of reasons. People who volunteer for phase II and phase III trials subject themselves to known and unknown risks with the prospect of no benefit. They will receive care that is no better or worse than the care they would receive if they did not volunteer, and they may have to pay for some parts of the research protocol."

Both the Novartis and CenterWatch texts provide information for individuals considering clinical trials. The information from CenterWatch will only be found by individuals actively pursuing enrollment in a clinical trial. The information from Novartis will reach a much broader audience. And yet, both fall outside the recommendations of Shamoo and Schwartz for regulating clinical trials because neither discusses a particular trial. By allowing such presentations, we risk any reward of the regulation Shamoo and Schwartz recommend.

**Crystallizing a Frame/ Undermining Review**

Shamoo and Schwartz have recommended the next logical step for regulating medical research—all medical research (not just research at federally funded institutions) should be reviewed by a (somewhat) independent panel. What this next step does not address, however, is how the information previously encountered frames how potential research subjects view the information associated with a specific clinical trial. With evidence stretching as far back as Wason (1960) and reviewed in a wide array of instances by Nickerson (1998), the confirmation bias is a robust conclusion of cognitive
psychology. Put generally, the confirmation bias refers to the tendency for an individual’s initial judgment to bias future judgments about the same issue. For example, once I have decided that the new administration will be a vast improvement over the old one, others will be hard-pressed to convince me otherwise. I may summarily dismiss new information, discount the weight of new evidence, or seek out only confirming information. Whatever the mechanism, once an initial judgment has been made, future judgments are more likely to follow suit.

Neither of the texts quoted above is related to a specific trial and yet both, to one degree or another, encourage the therapeutic misconception. Novartis tells a story of success, how a woman without hope entered a trial and was given medications that improved and extended her life. While some are so lucky, they are like the prizewinners at charity raffle. Yes, these happy few “win,” but the purpose of the event was to raise money. CenterWatch emphasizes presumptive and imaginary advantages: Unproven drugs are not necessarily better, and the care in a research trial is no better than the care in the clinic. And yet the key words in their text are “promising,” “excellent,” and “free.” Like good marketing schemes, Novartis and CenterWatch encourage potential research subjects to view an unproven product as beneficial, not risky, as an excellent opportunity, not a dangerous prospect. Both texts, whether maliciously or not, invite a therapeutic misconception. Even though therapeutic misconceptions can take on a number of forms, any claim that a treatment currently being evaluated is beneficial will always invoke a therapeutic misconception. Even if physicians would recommend the same treatment if it was not in a trial, and even if the risks involved in a particular trial are minimal, to claim that the treatment is beneficial outstrips the available evidence--the reason a treatment is
the experimental arm in a clinical trial is because of a lack of evidence of effectiveness. And yet, because these texts are independent of a specific trial, they are exempt from IRB review.

**A Regulatory Sisyphus?**

Beyond the regulation recommended by Shamoo and Schwartz, the next step might be regulating discussions of clinical trials even when they are unrelated to specific clinical trials. By so doing, research subjects might not be invited, as they are by CenterWatch and Novartis, to view clinical trials through a misleading frame. So, for example, let CenterWatch provide information, but have it reviewed by an IRB. Let Novartis advertise its brand so long as it avoids any (unreviewed) discussions of clinical trials. This expansion of regulation, however, would be misguided. Continuing the slow creep of regulation would cost time and money, and it is unclear what goal could reasonably be achieved. For example, there is no reasonable hope to regulate *all* discussions of clinical trials. Further, it's unclear how to judge an advertisement fairly. For example, would it be acceptable for a company to invert the Novartis’ strategy by emphasizing the costs of waiting for drugs to be approved. Such an advertisement would not technically be about clinical trials, it would be about the costs of waiting for approved drugs.

While needed, universal regulation cannot confront the information that invites patients/research subjects to view all clinical research as beneficial. The damage to patient/research subject understandings of a clinical trial may be done BEFORE the patient/research subject is considering a particular trial. The value of this regulation is
limited by its reach—by the time patients consider particular clinical trials, they may already be sure how good it will be for them.

