We have met the enemy and he is us!

I would like to return to the subject of over regulation and how it is sometimes of our own doing. My editorial on the broken clinical trials program generated a fair amount of discussion, including at my own institution. In an article written about the editorial, Dr Alan Sandler provided a startling additional piece of information. At one institution, 87 steps and 29 signatures were required to launch a trial (Helwick, C. *Oncol. News Int.* 18, [2009]). There are no regulations that require so many signatures. Since my editorial and the article were circulated to all relevant committee members at Yale, I was invited to attend a discussion of the problem at a Cancer Committee meeting. It was a lively group and they had a good discussion hoping to improve the protocol review and approval process at Yale, and dearly hoping we didn't require 29 signatures for approval (we didn't). Near the end of the meeting, someone asked, "Why do we have to submit cooperative group protocols to our Human Investigation Committee (HIC) when they have been reviewed by the National Cancer Institute's central Institutional Review Board and many other committees, and are essentially unchangeable by the time they arrive at our place anyhow?"

A member of our HIC answered, "You know, we always wondered why you sent them to us to review because we don't really have to review them." A hush fell on the room. People looked at one another. Investigators had assumed these protocols needed HIC review and routinely sent them into the process. HIC members thought they did not but took the submissions as a request for a review. Neither one had said anything to the other. Both were doing a lot of unnecessary work.

In my April editorial on the use of approved drugs in non approved ways, I highlighted another problem that occurs in our highly regulated environment, which is the assumption that everything we do needs FDA input and approval (DeVita Jr, V. T. *Nat. Rev. Clin. Oncol.* 6, 181 [2009]). In the case I described, investigators were intending to ask the FDA for approval of a new use for drugs that have been around for many years and are safe.

If you ask the FDA to define a strategy for you they will, and they may define a complicated set of steps. However, you may not even need to ask. They actually have better things to do.

I came across a small article by Thomas L. Schwenk in volume one, issue one (2009) of *Journal Watch General Medicine* entitled "A critique of clinical practice guidelines". I gravitated to it because I dislike practice guidelines. In my view, they are too restrictive in rapidly moving fields. Schwenk was commenting on guidelines in the cardiovascular field, but the general principles are the same. He cited a study of the evidence underlying guidelines developed by committees appointed by the American Heart Association and the American College of Cardiology (Tricoci, P. *et al. JAMA* 301, 831–841 [2009]). In short, since 1984 there have been 7,196 recommendations on 22 topics for 56 clinical practice guidelines. The number of recommendations increases by almost 50%, and the levels of evidence for guidelines decrease with every iteration so that the majority of recommendations are now made on the basis of opinions and case studies. Schwenk says, "Clinical practice guidelines, once spare and elegant in their creation, dissemination and application, have become commonplace, tedious and of questionable clinical relevance." The recommendation to correct this was to replace all members of guideline committees at each iteration, especially the leadership.

These are all examples of things we do to ourselves. They brought to mind my favorite cartoon of all times 'Pogo'. In one famous cartoon, Pogo was commenting on the politics of the 1970s in the US. He is standing on a platform in front of an inclined mirror looking at his image and seems startled, his hat is seen flying off. He says, "We have met the enemy and he is us!"

In the three examples I used above the enemy is us. That is the bad news. The good news is anything put together by us can also be disassembled by us if we are willing to ask 'is this really necessary?'

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Competing interests
The author declares no competing interests.