expert roundtable »

GPP2: Good Publication Practices for Sponsored Medical Research: Elevating the Integrity of Scientific Communications

Moderated by **Marvin Moser, MD**[1]
Discussants: **Bryce McMurray**[2]*; **Carol Sanes-Miller, MS, CMPP**[3]*; and **Yvonne Yarker, PhD, CMPP**[4]*

The following Expert Roundtable Discussion was held on March 22, 2010. Dr. Marvin Moser from Yale University School of Medicine moderated the topic "GPP2: Good Publication Practices for Sponsored Medical Research: Elevating the Integrity of Scientific Communications" with Bryce McMurray from Wolters Kluwer, Carol Sanes-Miller, MS, CMPP, from AstraZeneca, LP, and Yvonne Yarker, PhD, CMPP from Scientific Connexions, and Treasurer of ISMPP participating.

The discussion focused primarily on: (1) organized efforts to elevate the perception of collaborative medical publishing of industry sponsored research, (2) transparency of authorship of medical journal articles, ghost writing and scientific writing assistance, (3) duplicate publication of clinical trial results, (4) integrity of journal articles sponsored by the pharmaceutical industry, (5) omission of relevant data which might indicate bias, and (6) appropriate disclosure of conflicts of interest. (*Med Roundtable Cardiovasc Ed.* 2010;1(2):120–127)

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**DISCLAIMER: The views presented by Bryce McMurray, Carol Sanes-Miller, and Yvonne Yarker, PhD do not necessarily reflect the views of their employers, Wolters Kluwer, AstraZeneca, LP and KnowledgePoint360 Group, respectively.*

DR. MOSER: For the past four or five years, authors, editors and publishers have been concerned about the growing tendency for scientific articles to be signed off by a prominent physician who may not have taken an active role in writing the paper. They have also been concerned about the duplication of reports: a single study is finished and five or six articles result. Finally there has been concern about transparency of authorship, especially with publications sponsored by industry.

A discussion on elevating the levels of collaborative medical publishing of industry sponsored research is certainly appropriate and of interest. Such discussions have been held before by other people, but we hope to put forth some different ideas. In 2009, the International Society for Medical Publication Professionals (ISMPP) convened a steering committee to update the Good Publication Practice for Communicating Company Sponsored Medical Research (GPP) originally published in 2003. The GPP2 update was published in the *British Medical Journal* last November.[1] This is the most exhaustive attempt to clarify some of the issues of transparency, duplication, and authorship.

I'm Dr. Marvin Moser, Clinical Professor of Medicine at Yale, and the Editor in Chief Emeritus of *The Journal of Clinical Hypertension* (the *JCH*), the journal of the American Society of Hypertension and Editor in Chief of *The Medical Roundtable*. And as an editor of the *JCH* for ten years, we were constantly concerned about some of the issues that we'll talk about.

With me today is Dr. Yvonne Yarker, who is Senior Vice President, Medical Communications at Scientific Connexions in Newtown, Pennsylvania. She has had more than 20 years of experience in medical communications and is Treasurer of the International Society for Medical Publication Professionals. Also with me is Bryce McMurray, who heads the global medical communication business for Wolters Kluwer, and has been active in publication planning and medical communications, also for a good number of years. And Carol Sanes-Miller, who is a medical publication professional with more than 25 years experience in publications, including 15 in publication planning and development in industry.

Welcome to you all, you bring a variety of expert opinions to this discussion. I'd like to start out by discussing the whole question of so-called "ghost writing." How much has this occurred in the industry, is it common, is it being abused? In your judgment, how often do articles get submitted to journals that were primarily written by science writers, who were hired by an agency, which was hired by a pharmaceutical company, and then signed off by a physician, usually a well recognized physician? Your comments?

DR. YARKER: Based on my own experience through my work in medical communications, I don't recall any papers that were "signed off", if you like, by a physician or an expert. For all of the papers that I have been involved in, and that my colleagues have had involvement with, the investigators of the clinical trials provided input throughout and we spent time speaking with them to make sure that we captured their opinions.

Having read the literature and the general media, I think there is misunderstanding and confusion around the term "ghost writing" and how that's defined.

DR. MOSER: Would you define what these are?

DR. YARKER: Yes, at ISMPP[2] and in GPP2[1] we define ghost writing as the undisclosed use of medical writing assistance. The consensus from many other professional guidelines and reports (such as those from the Association of American Medical Colleges,[3] the Institute of Medicine,[4] and the European Medical Writers' Association[5]) is that transparent and disclosed collaboration between professional medical writers and investigators is not ghostwriting, supporting the need for full disclosure of all contributors, including medical writers.

DR. MOSER: Do you think it's enough, assuming that the authors of these articles do look at them and do interact with the writers, do you think that's enough? Should a physician who does a particular research project depend on scientific writers to write the paper for them?

DR. YARKER: I think you can look at that in many ways. One example that's often given is that a physician or an investigator who conducts a clinical trial doesn't do all the work on the clinical trial himself or herself. For example, there are individuals who collect the data, such as blood samples. There are others who have statistical expertise, who handle the statistical analyses. Then there are people like me and others who have a particular skill in being able to communicate the information clearly. So we all participate in trying to make sure that the clinical data is collected, analyzed, presented, and disseminated in the best way that it can be.

> ***"I think it's been an evolving process and I think it's a good one. Moreover, transparently acknowledging a medical writer's contributions clearly highlights the fact that this is a legitimate area of scientific endeavor."***
>
> *~ Carol Sanes-Miller*

DR. MOSER: Bryce and Carol, do you share that optimistic opinion about what's going on with scientific writers—let's not call them ghost writers?

MS. SANES-MILLER: I believe that if you illuminate the fact that a medical writer is involved by disclosing the writer's contributions, the writer is no a longer ghost. I think I'm old enough to be aware of several well-publicized cases in the literature and media that highlighted the problem you address. However, the organizations that I've been involved with over the last 20 or so years have moved in the direction of showing contributorship, acknowledging when a medical writer or editor has been involved. It has been an evolving process and I think it's moving in the appropriate direction. Moreover, transparently acknowledging a medical writer's contributions clearly highlights the fact that this is a legitimate area of scientific endeavor. Some medical writers are not necessarily researchers themselves, but are perfectly qualified to help other researchers put their content into clear and concise publications.

DR. MOSER: Bryce, what's your feeling about this?

MR. MCMURRAY: Yes, I think I'd concur that I've never seen a case where an author simply put their name to an article that had been written at the direction of a drug company. I think that may have happened, but I don't think at any time it was ever a common practice for that to take place. The sort of articles we're talking about would be review articles principally. Obviously in the case of a clinical trial, the principal author is usually the principal investigator, and they participated in the design, conduct, and all aspects of this trial.

I think the International Committee of Medical Journal Editors (ICMJE)[6] criteria for authorship are very good in a sense—a substantial contribution to conception and design, acquisition of data analysis and interpretation, drafting the article or revising it critically for important intellectual content—what are we going to say in this paper? And then final approval of the work to be published.

So they stand by that work, they stand by the science, and as Yvonne said, lots of people may have contributed to the execution of the study, and to the communication. They all bring their particular skills and experience to that. They all should be disclosed, their roles should be fully disclosed, but the notion that somehow these ghost writers sit there and sort of dream up the

right interpretation with the pharmaceutical marketing people standing behind them really isn't the case. I do think that that has been a picture that's been painted somewhere in the press, that simply doesn't reflect the way that the industry really operates at all.

MS. SANES-MILLER: Yes, and to your point, we have very careful processes in place regarding how to develop a manuscript when working with internal and external researchers, and in providing writing support or allowing there to be writing support. We make sure that all the appropriate steps take place so that the publication content is driven by the scientific authors, not by the medical writer.

DR. MOSER: Let me give you a personal experience based on more than ten years with *The Journal of Clinical Hypertension*. There have been instances where I'd call a doctor and say, "I've just reviewed your article on XYZ drug, or whatever procedure, and I'm sending it back. I edited it a great deal," and he would say, "Well, what paper is that?" And I would tell him, and the answer was a, "Well, um, uh, um," and I'd say, "Well, did you see it?" and he'd reply, "Yes, I think I saw the paper a couple months ago. Send it back to me and let me take a look." Then when he gets it back with major corrections, he says, "That's great, that's fine, thanks a lot."

Now that reflects to me that at least some of these authors, and I'm not certain how many, but enough, really don't pay much attention to papers written for them by science writers—who are very good by the way. I can always tell when a science writer is involved, because the references are numerous and complete. In most of these articles, the data are clear, they are correct, there's rarely, if ever, any fudging of data. But papers often suffer by omission—in other words, such-and-such study with drug A showed that such-and-such happened—but frequently a sentence or two that says other studies with drug Y also showed the same thing are often missing. Am I being too critical?

DR. YARKER: I agree that this is quite a changing environment in which we are working. It's certainly changed a lot since I began back in the 1990s in terms of guidelines, best practices, and ethical policies. I think it's still an evolving process. I do agree that if there are any differences of opinion in a research area or if there are limitations to the study, for example, they certainly should be reported. Using guidelines like the CONSORT Guidelines,[5] the ICMJE[6] Uniform Requirements, and GPP2[1] all help to set the stage for the most appropriate way of reporting clinical data.

I certainly agree that there are missed opportunities in this area, and that we still aren't at the place we need to be.

DR. MOSER: Yes, my major problem is that one or two sentences sometimes clarifies everything. A whole paper could be very positive about a procedure or a drug, but if there had been a paper three months before on another drug or another procedure, which produced similar results, that is often omitted. And again, it's not fraudulent, it's just omission. This has concerned not only myself, but we've been in touch with authors and editors of other journals, and this seems to be quite prevalent.

DR. YARKER: I think this happens in all areas of reporting research; nobody's perfect. Everyone should be striving to put their research into context. Even when I was doing post-doctoral work, and learning about literature analysis and how to report your own data, we were taught that you should be reporting not just the strength of your trial or your data, but the limitations as well, and whether the results support or contradict other published data. So I think that's always been the case, regardless of whether you use medical writing support or not.

MS. SANES-MILLER: Right.

DR. YARKER: Whatever area of research you come from, whether it's academic or a pharmaceutical company or elsewhere, you should be striving to do that.

DR. MOSER: Any other comments about this?

MS. SANES-MILLER: Actually, yes. I totally agree with you on that, and I think part of it reflects the fact that you've got a group of people working on it as well. Additional pieces of information should be contributed by all the members of the team that's putting the publication together, the authors and the medical writer. In many situations, for example, the medical writer may not have clinical expertise, and must rely on the clinician-authors to provide appropriate context. This is particularly true with respect to the introduction and discussion sections of clinical trial manuscripts. In the manuscript review process, if errors of omission are identified, they should certainly be addressed and rectified appropriately; disclosure of study limitations are a perfect example.

DR. MOSER: Yes. I'm not saying medical writers are the only ones who do this. You've been at meetings where a new report on a new drug is presented as if it's a major new discovery. Yet three months before, the same person may have reported on the same study, which also sounded like it was something very new. There are duplications and omissions at many meetings. I'm saying it's prevalent throughout, not just with medical writing. Bryce, do you have a comment about it?

MR. MCMURRAY: Yes, I think there is obviously a certain aspect to human nature to do that. As you say, nobody's perfect, and you've got to make sure that you're completely fair and

balanced. One thing I think that is a good movement that I see in industry is to lessen the involvement of the marketing group within a drug company on scientific publications and align publications more closely with R&D. I know that many companies are doing this, I know other companies are considering it. Just from the point of view of making sure that you're completely scientific, completely balanced, that's a good move, because you've potentially got an automatic sort of conflict of interest situation if the marketing group is involved.

So I do think that to create the best possible environment, to get the most balanced and the most accurate communication of information, there is a responsibility on all of us to reflect on that balance, as Carol was saying, at all stages of the publication process.

DR. MOSER: Yes, and separating the marketing from the other groups is a very good idea.

MR. MCMURRAY: I think so.

DR. MOSER: I think it's very good. So you all believe that we're making a lot of progress on the problems of having non-authors becoming involved in papers written by science writers. I think many of the authors have been alerted to the fact that perhaps they're not paying as much attention as they should. They get these beautifully written papers with superb references, in very good English, by the way, and they say, "Hey, this sounds pretty good," and they just put their name on it. I hope that practice is less and less frequent in the future.

MS. SANES-MILLER: I don't think that exists anymore. Although I can't speak to the processes in any specific medical communications organizations, I do know that whenever we are working with a medical writing group, we start with an initial conversation with our authors, documenting the conversation. The outline is drafted following those initial conversations, so that the authors are in at the very beginning, and drive the direction of the content long before it's on paper.

DR. MOSER: Yes, I hope that continues, because I said, my experience suggests otherwise, not universally, but enough to be concerned. As I said, several other journal editors and publishers have reflected the same feeling.

Well now what about conflict of interest and disclosure. Let me give you a recent example of an article that was published. It appropriately revealed that the lead author received an honorarium; and thanked Susie Jones and John Smith for help with writing the article, which means they wrote it. It acknowledged that three other authors were members of the team at XYZ Pharmaceutical company. This was full disclosure. I ask you, who would read something like this in a paper and believe its conclusions? That's disclosure, but can the results be truly unbiased?

> ***"How much protection should the doctor get from possible bias? Is he sophisticated enough..."***
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> *~ Marvin Moser MD*

MS. SANES-MILLER: Where does one begin here? Clearly, your example is inappropriate in a number of ways.

DR. MOSER: This paper was in a very good journal. The paper wasn't bad by the way. But by omission, it didn't discuss a lot of things that may have altered the conclusion.

MS. SANES-MILLER: The first issue, the honorarium issue—that was one of the topics that GPP2 obviously tried to tackle. We fairly quickly came to the conclusion that no honorarium should be paid for development of publications. And many of the organizations, if they haven't already, are bringing their standard practices along in line with that.

DR. MOSER: That's great, if that's followed through and hopefully it will be.

MS. SANES-MILLER: There was an exception, however, with respect to reimbursement for expenses. The consensus among the GPP2 Steering Committee was that if you are asking somebody to go to a scientific meeting to make a presentation and they weren't previously intending to attend that meeting, for example, reimbursement for their expense by the sponsor company would be appropriate.

DR. MOSER: That's fair. I think we can all agree with that.

DR. YARKER: I don't remember for at least the last five or more years paying honoraria to authors for manuscripts, certainly not in the area that I've been working in. It's been a policy of ours for several years and we've tried to advocate this with our pharmaceutical company clients.

There have certainly been queries from some authors who have had an expectation of being paid, but I think that the environment that we work in now is much different.

DR. MOSER: I think that's very good advice. Bryce, you were going to say something?

MR. MCMURRAY: Yes, just to back that up from Yvonne, we occasionally have requests from authors, who will come to us and say, "Do I get paid for XYZ?" And we feel it's our duty to point out that that doesn't fit with the right practice. Not very many now, but you do get the occasional person who will still ask that. As you say, in the past people did get that, but no, that is completely out of the question now.

DR. MOSER: What about the physician who's a very busy guy, follows disclosure procedures, and forgets the

honorarium; perhaps we've settled that. But there's a medical writer who wrote the article, and three of the five authors are employees of a pharmaceutical company. How much protection should the doctor get from possible bias? Is he sophisticated enough to say, "Wait a minute, I'll read this, but I think it's probably a little biased on the part of drug X or drug Y." Do we have to go any further than this in disclosure? Because some of my colleagues, when they get up at a meeting, with a disclosure slide wrote out that they are a consultant or a member of the advisory board of every pharmaceutical company in the United States. They may list 25 companies. Is it irrelevant or is there still something else we should do about the specifics of disclosures?

DR. YARKER: There are differences of opinion about what constitutes appropriate disclosure. If you look at different journals and different meetings, they have quite different requirements for what to disclose: over what period of time, within certain dollar values, and so on. ICMJE has gone some way to try and institute standardization around disclosures, but there are still quite a few differences from journal to journal and meeting to meeting.

My own view is that there are certain elements of disclosures that may be valuable. But just because a relationship is disclosed doesn't necessarily mean that the paper or talk is biased—but as a reader I'd at least like to know and be able to make my own decisions.

MS. SANES-MILLER: Yes. Because at the time we were developing the GPP2 guidelines there were no widely accepted standards for disclosure, we advocated greater, rather than lesser disclosure; though this area, too, is evolving.

DR. MOSER: There's a question that comes up, how much protection does a doctor need against this? Is he sophisticated enough to read an article or listen to a lecture and say, "Okay, I know they're trying to make a point, because I know they manufacture this product or this procedure." Do we need more definitive information than what we have today or is it enough? Anyone?

MR. MCMURRAY: I think that probably doctors are sophisticated enough to understand that, obviously, if a pharmaceutical company has sponsored some research, and someone is a lead investigator; there is an inherent potential for bias, and I think they can accommodate that. I think possibly the area where there has been some risk in the past, which again is no longer the case—it's simply publication bias; i.e., not all of the studies that were conducted were published or disclosed in a public form in any way. And I think looking only at the positive studies or a disproportionate number of those requires protection. Obviously now with the new rules on disclosure with clinical data, we're getting away from that.

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> *~ Yvonne Yarker, PhD*

My own experience with physicians is they are at least sophisticated enough to be able to take all of the data from the different manufacturers and so on, on balance, and make their own minds up about the particular advocacy and safety of a procedure or medication. I think most of them would be a little bit insulted in some respect if they thought that they needed protection in the same way as the layperson. But as I say, publication bias obviously had the ability to distort the picture in the past.

DR. MOSER: What do you think, Carol?

MS. SANES-MILLER: I think in the context of the shifting environment, the combination of clinical trial postings and individual author disclosures on publications allows readers to put two and two together. Light is shed on areas that were previously undisclosed. Interestingly, journal publication bias (i.e., disproportionate acceptance by journals of "positive" relative to "negative" clinical trial data) exacerbates the problem, as companies *appear* to be hiding less favorable data. On the other hand, we need to rely on the peer- review process, which should ferret out any inherent over-enthusiasm you might see or might suggest could be coming from internal versus external authors. Furthermore, I would ask if is appropriate or fair to taint pharmaceutical company employees as being lesser scientists than academic investigators? Good science is good science, no matter who produces it, and the ability to publish those data should not be disallowed simply because the investigators worked within a pharmaceutical company as opposed to an academic institution.

DR. MOSER: Yvonne?

DR. YARKER: Yes, I think that Carol makes an important point about who should be an author and who is able to present the data appropriately. Whether you work in a pharmaceutical company or in an academic environment, if you did the work and you qualify for authorship using the standards that are available to us right now, then certainly you should be an author.

DR. MOSER: Yes. First thing, let me get something very clear, I think the pharmaceutical industry does some great research. And I think without them, many clinical studies would never be done. Obviously the government can't do all of them, and many academic centers don't have the wherewithal. So I think a lot of this is necessary.

My only problem with pharmaceutical company reporting of research

has mostly to do with my colleagues, not the companies themselves. The company will release data and my colleagues are the ones who work with the science writer or write the study themselves. I must admit, I have never used a science writer, not because I don't think they do a good job, but because I like to be hands on. But some physicians will allow themselves to be put in a position or just saying, "This looks ok," because it's easy.

So I personally am not blaming the pharmaceutical companies. I'm blaming some of my colleagues for putting their names on papers that maybe they've seen and had some input, but they haven't critically reviewed them, because maybe they're too busy or doing too many studies.

Most of the omissions that I have found, and still do, by the way, come not from science writers; they come from academic physicians who should know better. The impact of a study will usually not be reduced by merely saying, "Another trial appeared to report the same finding." Now that clarifies my position.

DR. YARKER: I think there have been omissions across the board on how data are sometimes presented. Whether it's the pharmaceutical company or academia or elsewhere, nobody's perfect and nobody can claim that they have always presented their information in the most accurate and balanced way. But I think now there are many standards and best practices around the business of reporting of research data. In our business we need to be aware of them all, whether they are legal and regulatory requirements or whether they are best practice guidelines like GPP2.

DR. MOSER: I think all of you have done a great job in clarifying this, and these new GPP2 guidelines that were published in *The British Medical Journal* certainly will be very helpful for people to refer to.

You may have seen data from Stanford recently on prohibiting their non-full-time faculty from giving lectures with slide packs provided by industry. You are aware I'm sure that there are many physicians who have been giving lectures based upon a packet of slides provided by a company, and told that they can't vary from those slides because of fear of FDA guideline restrictions.

I'm concerned that someone would go out and give a lecture with a slide pack from industry with some good scientific information, but clearly a beginning, a middle, and an end of a message. So I'm thrilled that Stanford did acted to curb this practice. I know that several other medical schools have done it, and that moves toward what you all are working for, for good practices.

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>
> *~ Bryce McMurray*

Alright, one more item that has been annoying to many publishers and editors, the duplication of results. A study is done, it's a 12-week study of XYZ versus Y, a paper is published. The company sets up a publication schedule of six papers, one on young versus old, women versus men, black versus white, etc. Six papers emerge, all of which say, "The protocol has been published previously, but in summary it is…" and they are sent out to six different journals.

Is that necessary? Should multiple publications be reserved for large, multi-year studies with many different endpoints? Should duplication of studies be limited?

DR. YARKER: I think there are several things to consider. In GPP2, the recommendation is that the full paper from a clinical trial should be published first before sub-analyses or an individual center's data are presented, and I think that's an appropriate thing to do.

I think the difficulty may come in some of the bigger, more complex studies, where the journal has word limits or figure limits, or other elements like that that you have to consider, just practical considerations about how you get all of that information into, say, 3,000 words.

MS. SANES-MILLER: Yes. And the issue of multiple languages, as you move forward. I think one of the things that helps, and again falls under disclosure, is the recommendation to tie these to the clinical trial registry numbers that are out there, so that it will be clear which publications derive from specific studies. If you tie the publication to the appropriate study number "XYZ," the reader is alerted to the fact that multiple publications may have derived from any specific clinical trial.

DR. MOSER: Do you think it's still a major problem? Do you think anyone has really addressed the multiple publication problem?

MR. MCMURRAY: One comment I can make is that I think, when we're talking about research conducted in the USA, or in Northern Europe, all of these issues are being addressed. One area I know that we do have a problem with is research conducted outside, you're still getting the same study being submitted to multiple journals.

Certainly for the source of drug company-sponsored research that we traditionally talked about, the point about including the registry number, the guidelines that Yvonne spoke of, where you published the primary paper and so on is important. And then if it's appropriate, subsequent analyses, that by and large may follow. But

with all of this, I think there's a general problem of education outside the, if you like, Anglo-Saxon sphere and outside of Northern Europe; because, for instance, working in China and other places we're still seeing some of the bad practices, and duplicate publication is certainly one that we've had some experience with.

DR. MOSER: Maybe I shouldn't ask this question, but do you often get approached by a company saying, "Look, we just finished this 12-week study on our drug and it looks like it's really very effective in reducing progression of renal disease. We'd like you to outline four possible publications and give us the journals you think they ought to be sent to?" Do you confront that often?

MR. MCMURRAY: I can't say it's a common occurrence. I mean, again, there could be a legitimate reason for talking about that—if there were a primary publication and subsequent analyses that were important. Some drugs have mechanisms of action that implicate different systems that are of interest to different audiences, so there can be quite legitimate reasons to do that. But as we've said before, you should follow the rule that's in the ICMJE guidelines, and always disclose the registry numbers, so that people can clearly see where this research has been reported before.

I suppose the case of thinking about what the intent there is, if that's justified according to what they're trying to report, then it can be okay to publish different analyses in different places. But if it's merely being done to create a bigger footprint other than is justified by the studies, then no, that would not be regarded as good publication practice. So you'd have to look at each case.

DR. MOSER: Are you still seeing this kind of request?

MR. MCMURRAY: I can't think of one lately that I would say has been driven by simply the desire to get multiple publications. I think where multiple publications do occur, there's usually a pretty good justification.

DR. MOSER: Okay. I'm thinking of a couple of instances with angiotensin receptor blockers, for example, where six publications came out of a simple 12-week study showing efficacy in different subgroups. This was a good drug, but—six publications. My guess is that this is not an isolated instance. I am glad that your guidelines addressed this problem. I would hope that companies and authors would pay attention to these.

Again, this is not simply a problem of a company, it's a problem for the people who undertake to author the articles. They should say, "Well, wait a minute, you covered that in three other articles."

DR. YARKER: I guess the difficulty is when the authors submit their manuscripts to different journals. How easy is that to monitor for you as a journal editor?

DR. MOSER: To journals with different readerships—one GP journal and one cardiology journal, for example, it may be difficult.

DR. YARKER: The difficulty for the journal editors is keeping track of the multiple submissions and publications by different journals. It's hard for anybody to be alerted to the fact that there are multiple publications coming from a single study. There are certainly occasions where it's valuable, as Carol mentioned. Again, if you go back to the GPP2 guidelines, the recommendation is that the full report appears first.

DR. MOSER: Well, I gather from what you're telling me and from reading GPP2—a lot of work was put into it, by the way—that things are moving along in the direction of improving the ethics of reporting, not only transparency, but in judging whether transparency means anything. I gather we're making a lot of progress in that area. Is that a fair statement?

DR. YARKER: I think so. A lot of work has been done by many different organizations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Writer's Association (AMWA), ISMPP, and others, to try to set some ethical standards and policies by which these publications should appear. The ICMJE, in particular, has been instrumental in setting guidelines and standards for submitting and developing manuscripts. There are a number of guidelines that we use here internally to try and develop publications in the most compliant and ethically appropriate way.

DR. MOSER: And I hope you make certain to involve your authors often, right?

DR. YARKER: Yes, we do.

DR. MOSER: Keep bothering them, because they're all so very busy as I said doing other clinical trials. Some of them might ignore your requests and figure that you guys will do all the work, which you often do.

One final comment from each of you and then I'll summarize.

MR. MCMURRAY: Yes, well I guess I could just reflect on that last comment, you're right about informing and educating the authors as being one of the main things that we have to do. We're actually spending quite a lot of time doing seminars aimed at that audience. For physicians, if you want to process clinical research, if you want to be involved in the offering and presentation of these studies, these are the guidelines that we're following and explaining to them. So that's been very much a growing area.

I know a number of organizations doing that, and we're happy to play our role in educating, and hopefully creating a new image, and disabusing some of the myths. This is really evolving into a fully ethical and fully well-understood industry that as you say we believe provides a valuable contribution.

DR. MOSER: Yes, one comment about that, Bryce, the authorships of a lot of these papers is very different than it used to be. Many of you may remember that research used to be done by a handful of people in academia, because the studies never involved 22,312 people. Now the "research" is done in 300 small centers or private offices by physicians who may be very capable, but who but who just follow maybe eight or ten people as part of the study.

MS. SANES-MILLER: Yes. That certainly came up in our discussions as GPP2 was being developed. I don't think it's well recognized that when you have many people involved—as is common in large clinical trials—requiring various areas of expertise and contributions, the question of what constitutes authorship becomes much more complicated. Authorship is not just participation as an investigator; current guidelines require the "potential" author to make intellectual contributions to the study and at every stage of manuscript development and approval.

Who are the final authors on company sponsored research? Obviously not every investigator meets all authorship criteria, though the lead investigators will very often serve as authors on behalf of large study groups. I think that isn't well recognized in the external environment.

DR. MOSER: Carol, do you have any final comments about the overall picture, I know you're optimistic about what's been happening?

MS. SANES-MILLER: I am. I've been watching and participating in many of these changes over a long period of time. I began my career in editorial support for academic researchers; I worked in medical communications, and for the last nine years, I've worked within pharmaceutical companies. I actually am very optimistic. I've seen how hard my colleagues work to clearly and accurately convey good science, with ethically appropriate handling of the information. We are working to improve patients' lives with medicines that provide safe and effective treatments for difficult medical problems. I think that in some respects, industry is sometimes inappropriately disparaged due to the notorious examples. Not that there haven't been cases, but I think that most of us try to bring scientific studies to the literature in the appropriate way; evolving guidelines and standardization help us do that.

DR. MOSER: Okay, Yvonne, any comments?

DR. YARKER: I agree that we've certainly come a long, long way since I first began in medical communications 20 years ago. I think it is to the benefit of physicians and investigators who work on the clinical trials, it's to the benefit to the pharmaceutical industry and others who support the trials, and it is to the benefit of patients who are the ultimate recipients of the research. So we're now able to set higher standards and ethical best practices across all interested parties. If we look at ISMPP as an example, it brings together authors and researchers, medical writers, pharmaceutical companies, and journal editors and publishers. And there's often agreement on what best practices should be.

DR. MOSER: In summary then, I think that authorships of articles, duplication of publications, and omission bias primarily has been a problem that has bothered people for a long time, not just the last three or four years. It's never been a question of fraud or fudging of data, except in a few isolated cases. But I think these problems are now being addressed by not only professional writing organizations, but by industry, and certainly by academic institutions.

I trust that in the future a lot of the abuses that were quite common will become less and less common. And as I said some of the academic institutions are moving rapidly, not toward preventing pharmaceutical companies reports and research, which is very necessary, but toward moderating it a little bit and preventing it from being used purely promotionally.

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