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COMMENTARY

Role of Physicians in the Pharmaceutical Industry and Clinical Research Organizations: Take More Pride in Your Work

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Abstract

Physicians working in biopharmaceutical companies are key components in the successful development of new diagnostic and therapeutic developments. They have a high level of responsibility for the safe performance of clinical studies and for evaluating the efficacy of new potential treatments in patients. Recently, articles in highly ranked scientific journals have challenged this work. This article highlights the shortcomings of those views. In contrast, we document that the majority of the physicians working in the pharmaceutical industry provide extremely high-quality work, in part forced by the rigorous regulatory framework this work has to comply with nowadays. We promote an open (and critical!) discussion while sharing industrial views and opinions with colleagues from academia. Only by a constructive cooperation between both worlds, avoiding a black-and-white view, will we achieve an instrumental and effective way in developing new and affordable diagnostic and therapeutic tools that are truly helpful and affordable for patients. If physicians in the industry take more pride in their work, this would be helpful in fostering such an approach.

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Physicians working for biopharmaceutical companies or clinical research organizations (CRO) are in a difficult position. In companies, they are key components in the successful development of new diagnostic and therapeutic developments. Their input to the teams responsible for such projects is not limited solely to medical aspects, but covers ethical aspects and sometimes business responsibilities as well. Likewise, physicians working for a CRO have a high level of responsibility for the safe performance of their clinical studies and for evaluating the efficacy of new potential treatments in patients. Clearly, these physicians do not work in the typical environment of a hospital or a private practice anymore; however, in no way does this mean that their work is no longer relevant or important for patients.

Some of the more recent articles in highly ranked scientific journals, such as the one by M. Shuchman in the *New England Journal of Medicine*,[1] or in magazines, such as the *New Yorker*,[2] suggest that physicians in nonacademic clinical research have sold their soul to the "dark side of the power." These poor colleagues are brainwashed and all they can do is obey the orders of their management in order to maximize their personal

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or the companies' profits. However, this is a slap in the face of all physicians working in the biopharmaceutical industry or for CROs.

It appears as if some academic physicians and some people from other disciplines in academic positions have difficulties in accepting that there is an "alternative way" outside of academia, a way that is attractive to physicians who are enjoying the excitement and challenges of research and of clinical research in particular.

No, it is not just about the money but very often about nonacademic research approaches that enable them to effectively pursue responsible, very professional, and rather relevant nonclinical and clinical research activities. From our point of view, and we acknowledge that this point is a biased one too, colleagues such as Dr. Shuchman are taking the risk of having their integrity and motivations being seriously questioned if they try to put a negative image on physicians working in the biopharmaceutical and CRO environment by pointing out the negative events in their environment, while at the same time ignoring comparable events in academia. This is neither a scientific nor a logical and fair approach. Unfortunately, "independent" access to highly reputable media that could promote an open (and critical!) discussion while sharing industrial views and opinions with colleagues from academia is very limited. Articles from biopharmaceutical authors about the conduct and ethics in clinical research seem to be suspicious a priori and their activities are directly disregarded as being biased due to a conflict of interest.

We do assume that it would be rather healthy for all seriously science-centered discussions if the end of the ivory tower age could be proclaimed.

Just to get things straight: fraud and misconduct are in no way phenomena limited to the "bad guys" in industry. As we all know, these phenomena also exist in academia, so there is no need for anyone to cite numerous specific examples at this point. To our knowledge, the pressure to generate "positive" and publishable results while in an academic position has led to most of these academic cases in the last years. Having been in diabetes research in academia for many years before establishing and running a clinical research institute for 9 years now, which specializes in early phase diabetes and obesity research, our clear experience is that, since we started the nonacademic research institute, we have been expected to adhere to much more rigid, formalized rules, regulations, and quality expectations than we ever had to adhere to during our times in academia. In that sense, data generated nowadays are probably much more robust than in former times. From our own experience and in knowing both worlds very well, we have difficulties in understanding the concept of "sinners" working in the industry/CROs, while "saints" work in academia.

From our own experience, the pressure to attract and run clinical trials to ensure the continued funding of a position in academia can be very high and, for some of us, was much higher at universities than it is nowadays. In that sense, academic sites are not more independent than their pharmaceutical–industry clients than CROs. If physicians and other scientists from either side communicate directly and openly with each other and put aside all prejudices, we could be much more instrumental and effective in developing diagnostic and therapeutic tools that are truly helpful and affordable for patients.

Physicians in academia also have a tendency to disregard the scientific credibility of their colleagues working in a nonacademic world. However, an evaluation of the number of papers (also in highly respected journals) reporting true scientific progress but being published by physicians/scientists working in companies might be an eye opener at this end. We can say that at least for our institute, we have a considerable number of articles published by our contract research institute each and every year.

An often repeated complaint raised by colleagues in the academic world is that more and more studies are performed at CROs than in academic centers/hospitals. Clearly, this also diverts financial resources from academia. As far as we can tell from our quite long history in clinical research, there are some core reasons why academic centers are not considered for many clinical studies. The complex regulatory and formalized environment of professional clinical research, particularly formalized and demanding when it comes to quality management, is creating a layer of demands that are difficult to manage, to say the least, in an academic environment that comes with its own forms and formats of bureaucracy. We would be curious to see some head-to-head statistics about the quality of contract research work in academic versus nonacademic research institutions. Knowing from personal experience, there are a number of distractions that a physician in a standard academic setting has to deal with compared to a focused industry setting. It is the experience of many of those

who conduct clinical research in academia that, after the department head signs a study contract, the project gets passed on to a subordinate. This passing on of projects quite often continues until, finally, the least experienced ones perform the studies. In contrast, in many CROs, highly trained and experienced investigators run the clinical trials.

Even if the work and the quality of work provided by nonacademic clinical researchers are probably not recognized by many physicians, it is very transparent to their biopharmaceutical clients and to the regulating authorities. Within the professional clinical research environment, thorough monitoring and auditing processes are the norm and not the exception. Based on our personal professional careers, we conclude that clinical research could be run as effectively and efficiently if there was a mandate to do clinical studies partially or completely at academic centers. Any such mandate would very likely result in a substantial slow down of medical progress and in unaffordable new treatments, and we are not even talking about the impact on data quality here.

Is there a way out? Yes, of course. However, the way is not and cannot be characterized by inflammatory and toxic battles about who the better clinical researcher is and where the better clinical researcher works. Rather, the way out depends on accepting the fact that two are better than one. In other words, physicians from academia cooperating with their colleagues in the industry and CROs could generate the best possible scientific outcome, which would be more innovative and productive for everyone. Based on recent articles in the *New England Journal of Medicine* and the *New Yorker*, we have identified some room for improvement as far as the acceptance of the role of physicians inside pharmaceutical companies and CROs is concerned. It seems as if physicians and other clinical researchers working in the industrial environment should display more pride in their work and be more active in defining and establishing positions to foster a fruitful and helpful academic–nonacademic cooperation. Sticking to the "cold war" scenario of good academia versus bad industry can easily turn the scientific potential for medical progress and much needed treatments into a pile of useless trash. By the way, we have also read a well-thought out article published in the *New England Journal of Medicine,* which highlights additional constructive approaches regarding this topic.[3]

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Disclosure:

Lutz Heinemann is the chief executive officer of Profil in Neuss, Germany. Marcus Hompesch is the chief executive officer of Profil in San Diego, California. These companies perform clinical-experimental and clinical studies for a variety of pharmaceutical companies in Europe and the United States such as Novo Nordisk, Eli Lilly, sanofi aventis, Merck, Roche, Bayer, LifeScan. They do not own stock in these companies.

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