

PRO/CON

Our second installment of CaJEM Pro/Con examines a longstanding “hot” topic in research and emergency medicine. We asked our esteemed discussants:

SHOULD ACADEMIC EMERGENCY DEPARTMENTS COLLABORATE IN PHARMACEUTICAL INDUSTRY-SPONSORED RESEARCH?

THE DANGERS OF INDUSTRY-FUNDED RESEARCH IN EMERGENCY MEDICINE

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Historically, academic centers have been the venue for conducting important clinical trials. Teams of well-trained investigators functioning in well controlled settings have set the standard for rigorous scientific design and data interpretation in clinical trials. Institutional review boards have contributed to research subject safety and minimization of scientific misconduct. This system has been in place throughout time and we have seen many amazing discoveries. However, with rising medical costs and greater economic restraints, the academic centers have lost funding and turned to private sources of investment. The once clear boundary between industry and academic centers is now frighteningly blurred; even

worse, many drug trials are conducted entirely outside traditional academic centers. The pharmaceutical industry now runs much of the medical research in this country, but the question is: To whom are these companies and academics now accountable?¹

While academic centers have felt this tightening with budgetary constraints, the pharmaceutical industry continues to flourish. In 2000, \$2.5 billion were spent on direct advertising to consumers. Increases in the sales of the 50 drugs most heavily advertised to consumers were responsible for almost half (47.8%) of the \$20.8 billion increase in pharmaceutical spending in 2000. Despite strong revenues, the “research-based” pharmaceutical industry spends more on marketing and administration than it does on research and development (R&D). Since 1995, R&D staff of U.S. brand name drug companies have decreased by 2%, while marketing staff have increased by 59%. Currently, 22% of staff are employed in research and development, while 39% are in marketing.²

When looking at pharmaceutical sponsored trials, we must ask, “What is the motive?” The primary role of industry is to make money and the secondary goal is to promote public health. History has shown that when these two clash, the monetary motive may win.^{1 1} When clinical trials are successful, widespread support is achieved by publication in medical journals. This results in financial gains for industry and it may contribute to our patients’ health. However, some of this research leads to biased reporting. This is demonstrated by the increasing number of clinicians performing research for a specific pharmaceutical company and then becoming the “experts”. These experts travel the country and speak at a variety of conferences and “CME over dinner” meetings. These

same experts write most the reviews on the drugs they have researched. These activities can be quite lucrative for the academics involved, many of whom earn far less in their clinical practice than their private practice colleagues. Whether they want to or not, these experts become part of the pharmaceutical marketing machine, rather than part of the traditional unbiased academic review team.

Aside from the questionable credentials of what constitutes being labeled as an “expert”, the results and presentation of industry sponsored research may be dubious. The vast majority of the trials performed by industry have “positive” results.³ The spin put on the trial results is also equally positive. In many cases it is difficult to determine where the expert ends and the marketing department begins.^{4,5}

What is clear is that drug development is expensive. It is estimated that the average cost of bringing a new drug to market in the United States is about \$500 million. Multicenter trials are usually required to enter adequate numbers of patients. How do pharmaceutical companies manage these costs? Contract research organizations (CROs) are private consultant companies that organize these trials for financial gain. They are a clear winner over academic centers as they can set up trials for less money and allow speedier collection of data. For example, in 2000 in the United States, CROs received 60% of the research grants from pharmaceutical companies, as compared with only 40% received by academic centers.

Another less obvious advantage to using the CRO is that terms are set by the industry regarding methodology, which may not always be in the best interest of patients or of gaining an understanding of

the disease in question. Additionally, part of participation in working as an investigator is that there is typically no access to the raw data, and limited participation in data interpretation⁵.

As more drugs are developed and prices continue to escalate, we will continue to see more physician profiling and industry sponsored research. Ideally, we would be immune to the affects of “detailing” by pharmaceutical representatives. Critical appraisal of the literature would keep us honest and medicine would be practiced based on best evidence. However the pharmaceutical industry’s infiltration into daily practice is evidenced by physician behavior on a daily basis. Sigworth et al, in a study published in 2001, looked at the effect of pharmaceutical industry gifts on physician practice⁶. Residents completed a questionnaire, after which all of the items they carried in their white coats were inspected to identify pharmaceutical company brand names or logos. Nearly all of the residents had eaten an industry sponsored meal within the previous year (98%), believed that industry representatives had accurately presented their products (99%), and felt that these activities at least partially influenced their prescribing habits (91%). It is interesting that only 13% stated that they would be willing to wear a product advertisement *patch* on their white coats, like a NASCAR® driver. Yet nearly all of them (97%) were carrying at least one item having a pharmaceutical insignia, and about half of all items carried were branded (a median of four items per resident). The branded items most commonly carried included reference books (carried by 90%), calipers (85%), pens (79%) and information cards (70%). Most of these residents seemed to be aware of the influence of pharmaceutical representatives, but most also carried branded items.

The same marketing occurs on a medical school level. In an editorial in May of 2000, in the *New England Journal of Medicine*⁶, the author laments the decisions of major universities in the past few years to further strengthen their ties to the pharmaceutical industry. The question is asked: "What is the justification for this large scale breaching of the boundaries between academic medicine and for-profit industry?" The answer is money. The secondary effects of improved communication between industry and academic centers is clearly a secondary gain at best.

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REBUTTAL:

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I greatly enjoyed reading Dr. Stone's and Dr. Herbert's composition on pharmaceutical company sponsored research. While clinical trials conducted in academic medical centers were not immune to some of the problems of conflict of interest, it is a shame that so many of the important drug trials and so much funding for research is currently going to other, typically for profit, research corporations. Drs. Stone and Herbert also correctly note that marketing budgets have increased by as much as 50% compared to research and development research and development (R&D) budgets recently. Since the restrictions were relieved, pharmaceutical companies found that direct to consumer marketing is far more effective than physician marketing. In a sense, it is because of the paranoia that some physicians display toward any interaction with drug companies that the industry turned to direct marketing and discovered it was far more successful. Many physicians have driven pharmaceutical representatives away in a misguided attempt to prevent undue influence. Instead of working hard to convince physicians of the benefits of using certain medications, now drug companies simply have to convince a consumer that they want the drug that will allow them to run across a grassy field without being crippled by allergy symptoms! There is an old adage that suggests keeping your friends close, but your enemies closer. For those physicians who see pharmaceutical companies as the enemy, instead of driving them away from academic medicine, we should have kept them close and learned to interact