

Association of Clinical Researchers and Educators (ACRE)

Testimony before the Minnesota Legislature

Dear Representative Atkins and Senator Metzen:

Thank you for continuing your respective committees' hearings on the commercial aspects of health care in Minnesota. January 25th, 2010 will be a clinic day for me, so I will be taking care of patients as you hold your hearing.

We would like to provide you and the rest of the legislators in attendance at the hearing with the written opinion of the **Association of Clinical Researchers and Educators (ACRE)**, an organization of physicians, in opposition of bills HF491, HF1640, and HF1641, introduced by Representative Liebling, of Rochester, MN. ACRE's position is that the bills under consideration, if enacted into law, will harm patients and medicine.

Here are the major points we would like to emphasize:

- "Generics all the time" is a false economy.
- Newer medications are more cost efficient in the long run. They represent an investment in future health.
- Medical care decisions should be made by physicians and patients together, not anyone else.
- Physicians, especially in greater Minnesota and large medical groups in metropolitan areas, deserve free access to all sources of medication information with no restrictions – not from the State, not from HMOs, not from the federal government. Excellent medical care is built on this exchange of information, and partnerships between physicians and industry are integral to it.
- ACRE believes that the collaborative relationships between physicians and industry are moral, ethical and legal, bring value to medicine and to patients, and result in excellent patient care.
- ACRE does not condone unethical behavior in medicine, the examples of which are exceedingly rare.
- ACRE affirms that the work product of physicians includes clinical research and education, and that physicians should be paid for the work they do. It is not up to the legislature to determine the contractual arrangements of physicians for the work they do.

Excellent medical care requires clinical research and development, and it mandates the education of physicians on cutting edge technology and emerging therapies. Pharmaceutical and biotechnology companies bring to market medications and technology that benefit patients and are an integral part of this excellent medical care. In the simplest of terms, American medicine could not have achieved its phenomenal successes, nor would it have the promise to continue to conquer diseases, without these partnerships with industry. The constant attacks on pharmaceutical and biotechnology companies are therefore groundless and injurious.

Commercial Bias? – Bad Assumption

The principal objections to the marketing practices of pharmaceutical companies are that they provide physicians with erroneous information in overzealous attempts to sell their products, and that physicians who receive this information treat patients inadequately. Further, claims that “doctors get paid” by pharmaceutical and biotechnology companies “to increase sales” have dominated the media, and are perpetuated in publications, both in the lay and the medical press. And finally, peer to peer medical education, be it in print through medical journals, at medical education events with a continued medical education (CME)-approved sponsor, or at smaller venues such as specialist visits to smaller clinics, when sponsored by industry, has been labeled as “marketing”.

When one looks critically at the evidence to make these generalizations, one finds opinions, which then get quoted as fact, and which get perpetuated by re-publication. There is only anecdotal data of *possible* improprieties, and there are many accusations, most of which receive a lot of press, but then are found to be groundless. If physicians apply the rigor or “evidence-based medicine” to these opinions, they find they truly have no merit, and are indeed wrong.

As an example of how actual data flies in the face of these assumptions, consider:

- An analysis published in *The International Journal of Obesity* and financed not by industry, but by the National Institutes of Health (NIH). After analyzing weight-loss research conducted over four decades, they’ve found that the quality of data reporting in industry-sponsored research does indeed seem to be different from that in other research: It’s better. (*International Journal of Obesity* 32, 1531-1536. Oct, 2008)
- The research paper in the most recent issue of *Academic Medicine* by Michael Steinman and colleagues. They set out to prove that pharmaceutical company sponsorship of CME programs biased the presentation. They found exactly the opposite. Rates of perceived bias were low for the vast majority of CME activities in their sample and did not differ by the degree of industry support or other event characteristics. (*Acad Med.* 2010; 85:74–79.)

Where is the conflict?

Recent developments in American Medicine need to be highlighted:

1. Federal legislators have repeatedly leaked to national media outlets accusations of inappropriate behavior by very few individuals in medicine and industry. These accusations receive tremendous media coverage. When these accusations are appropriately reviewed, they are almost universally dismissed. They represent exceptionally few instances of questionable behavior, and even fewer instances of actual misconduct.
2. The Association of American Medical Colleges (AAMC) issued a mandate that all medical schools seeking to be recognized in the US, had to develop and implement “conflict of interest” (COI) policies. This mandate forced every academic medical center

into the use of a term that has become prevalent. The individual responsible for this mandate, Dr. Jordan Cohen, acted on his opinion that the *perception* of COI warranted such a system-wide measure. The task force he set up stated that "(AAMC) embraces the obligation of the profession to manage, through effective self-regulation, all real or perceived conflicts of interest." Most academic medical centers, following this publication in 2006, have had to develop and implement these "COI" policies. The practical implication from this document is that any medical education that does not come directly from a medical school is "biased", and therefore "suspect". It would be expected that the AAMC would adopt this position to discredit any other source of medical education in the United States. This has significantly hindered the dissemination of information on emerging therapies, which up until now was driven by grassroots education in the form of peer to peer education. Further, it has led to a generation of medical students who have imposed onto them another bias -- that of the AAMC -- that industry brings no value to medicine. ACRE is extremely concerned that the new generation of physicians will not provide the physician base to engage in clinical research and medical education as a consequence of this trend. ACRE is also concerned that the vast network of independent clinical research sites is being threatened by the "COI" movement. And lastly, ACRE asserts that peer to peer education with industry sponsorship has tremendous merit and does not represent a conflict of interest. ACRE wishes to highlight the conflict in "conflict of interest". It is a position that directly benefits the AAMC and its affiliated institutions to the detriment of all other medical education in the country.

3. The Accreditation Council on Continued Medical Education (ACCME) has implemented standards for the disclosure of working relationships and funding of CME that make medical education in the US a completely transparent process. ACCME accreditation is required to validate an educational session as valid toward maintenance of licensure or certification. The ACCME standards provide "transparency" to all CME in this country. ACRE agrees with transparency and the disclosure of working relationships that may impact an accredited program. ACRE feels strongly that disclosure should not be limited to pharmaceutical and biotechnology company working relationships. Rather, a detailed accounting of money paid by lawyers to expert witnesses, and that given by foundations, should be disclosed. ACRE strongly encourages that this complete transparency also carry over to medical journals, many of which do not consider huge payments to authors by trial lawyers, or individuals with anti-industry opinions, a conflict of interest.
4. In the *opinion* of some employees of the Office of the Inspector General (OIG) of the Department of Health and Human Services of the United States, a physician who provides education with industry sponsorship is no longer a physician, but a marketer. This office is responsible for forcing upon pharmaceutical companies mandates that severely limit the interaction of physician educators with their audience, when they work under industry sponsorship. The legal counsel for each large pharmaceutical company now must give approval for each slide that is to be presented at an educational venue to protect the company from the OIG. These lawyers, both those in government and those retained by pharmaceutical companies, have destroyed peer-to-peer medical education in the United States. ACRE affirms that physicians are NOT marketers. ACRE also

affirms that irrespective of the source of support, all peer to peer medical education has merit, and it advances science.

5. PhRMA, the association of pharmaceutical companies, has responded to the incessant attacks of COI proponents by implementing its own standards for physician-industry working relations. ACRE supports the efforts of PhRMA to provide transparency, but here again, has strong concerns about the restrictions currently placed on physician educators.
6. The American Medical Association's (AMA) Council on Ethical and Judicial Affairs (CEJA) has brought up three times in the past few years, the idea that medical education in the United States should be completely independent of any industry sponsorship. The democratic process of the AMA, its House of Delegates, which represents all of American medicine (all states, all specialties), has rejected this proposal every time. This has frustrated AAMC and the federal legislators that wanted the AMA to take a stance against industry sponsorship of medical education. ACRE supported the AMA House of Delegates in this decision, and it feels strongly that it reflects the position of the majority of American physicians.
7. The drug development process, as it currently exists, with the Food and Drug Administration (FDA) responsible for oversight, ensures that ALL medications that come to market do so only after rigorous clinical trials prove their value. This is the epitome of evidence-based medicine. Any drug in the market now has evidence that it brings benefit to patients. ACRE supports the FDA's role in ensuring that good science leads to better treatments for patients.

The developments above ignore that for clinical research to bear fruit, it must translate into the effective implementation of newer, better treatments. Putting clinical research and drug development aside, the role that pharmaceutical and biotechnology companies have played in the dissemination of medical information is significantly impaired by all these developments, and the implications that come from the use of the term "COI". A delay in the dissemination of information directly leads to a delay in the implementation of newer, better treatments, and it therefore causes patient harm. This is why some professional organization like the American Association of Clinical Endocrinologists (AACE) have rejected the term "COI". Physicians have a multiplicity of interests, or a commonality of interests, and there is no inherent conflict when physicians work with industry – not in research, and not in education. ACRE supports this position by AACE.

Newer treatments are an investment in future health

ACRE is not opposed to the use of generic medications when appropriate. But ACRE is definitely against not using newer, better treatments when they would be the best treatment for our patients. The appropriateness of treatments should be up to doctors and patients, not anyone else. As physicians who take care of patients, do clinical research and educate our peers about cutting edge medicine, those of us at ACRE want to focus the healthcare discussion on the higher future cost of not treating patients appropriately now.

Universal generic medication use is akin to not fixing the levees around New Orleans because of cost. An investment early on would have saved millions. The appropriate use of generic and patented medications represents an investment, and will directly lead to significant cost savings down the line. Newer, better treatments come to market after the FDA approval process, which always involves “evidence-based research”. New medications and technology add to the quality and life of our patients. In Minnesota, new medications are underutilized. Minnesota has the highest percent of generic medication prescriptions of any state, frequently to the detriment of patients. There is even a practice by third party payers to pay pharmacists for switching patients to generics. ACRE believes this practice by third party payers to be, at the very least, immoral, if not illegal. ACRE wishes to highlight the recent article in Mayo Clinic Proceedings by Dr. Simpson and colleagues, that clearly documented that treatment with atorvastatin (patented, newer medication) compared with simvastatin (generic medication) was associated with a reduced risk of cardiovascular events, reduced indirect costs, and a minimal difference in total costs to employers. Again, data argues against the opinion that generics are better and bring cost savings.

As an example, the cheapest medication for diabetes is generic glyburide. But this medication causes low blood sugar reactions, it causes worsening of diabetes control over time because it depletes the capacity of the pancreas, it leads to more 911 calls, more ER visits, more hospital stays for elderly patients, and more complications from diabetes. We know this because it was the only type of diabetes drug we had over the 1970s, 1980s and 1990s, other than insulin, and history tells us this old drug leads to all these problems. As physicians taking care of these diabetes patients, we are angered when they end up taking these obsolete medications, with the harm they cause, because they are “cheaper”. In reality, as tax payers, they cost us more. For patients there are human costs that never get factored in – the time off from work, the family stress, the lost driver's license after a low blood sugar reaction, etc. Newer medications for diabetes do not have these risks. They are better, and they are safer. They add to the quality and quantity of life for patients with diabetes. They deserve wider use.

Improving Minnesota's Health in a cost-effective manner

ACRE believes that a meaningful discussion on health care costs must include:

- The value of treatments, not the cost of pills
- The advancement of medical care with the rapid implementation of better, newer treatments by the use of all avenues of dissemination of information
- The harm of universal generic use
- The harm of limiting the flow of information to health care professionals from any source
- The overall cost of care:
 - the long-term consequences of not using the best, most effective treatments now, when this allows complications of chronic diseases to develop
 - the short term consequences of medication switching, which leads to more office visits, more labs, more time off from work, lost physician income (subsidizing countless hours of third party payer generated forms), and major patient inconvenience
- The cost to Minnesota tax payers of collecting data on the source of payments to physicians for work done legally (i.e. payments for research and education), which is currently just being collected without any purpose in mind.
- The cost of implementing any further data collection, and the need to validate a rationale behind it (again, forcing data collection for the sake of data collection is an incredible waste of resources)
- The application of a rigorous evidence-based approach to any financial decisions. Up until now the opinion of some individuals has dominated this discussion, with no data.
- The impact to the extended Minnesota economy that results from attacks on industry.
 - The cost of decreasing our tax base when pharmaceutical companies withdraw from doing business in Minnesota, which has created a hostile environment for them. Some companies, such as Auxillium, have chosen not to market in our state.
 - The cost of losing pharmaceutical company employees in Minnesota, adding to our unemployment rates, and further decreasing our tax base.
 - The negative impact on the restaurant and catering businesses, which traditionally have been integral to the gathering of physicians for peer to peer education.
 - The impact to other industries (ie. printing and media companies), who have lost much of the pharmaceutical and medical industry business.
 - The impact on medical education companies, whose educational products have been limited by a withdrawal of funds from industry.
- The cost to individual patients and their families – the human costs, which are always forgotten when we focus on pill costs.
- The value of physician-directed medical care that considers the unique social, educational and financial position of each patient in making health care decisions.

ACRE Recommendations

The proposed bills by Representative Liebling are superfluous, and reduce the 1991 reporting laws to a cost that Minnesota tax payers have to bear with no practical or usable outcome. HF 1640, in particular, is a drain of resources that would be best put to use elsewhere. This bill proposes that physicians be taught to do what they do for a living, and ACRE finds it insulting.

With regard to HF 1641, in its current form, ACRE agrees that “gifts” are not proper. But we do respectfully submit that the Minnesota legislature should specifically exempt meals provided in the context of medical education events as not being a “gift” that must be reported to the MN Board of Pharmacy. And we also submit that meals provided during detailing should also be exempted from the “gift” definition, since those physicians who choose to see drug reps get valuable, accurate information that helps them be better educated, and helps them provide better medical care. They represent a part of doing business for industry and physicians.

Conclusion

We wish to make you aware of the December 11, 2009 publication by Laurence Tribe, a prominent Harvard Professor, who brings into question the constitutionality of the 1991 reporting and gift laws, and the currently proposed bills by Representative Liebling, which, by virtue of imitation, have sprouted in other states, including Massachusetts. In this paper, Tribe makes this point:

‘...Remember the insights of Justice Oliver Wendell Holmes. Dissenting in *Abrams v. United States*, he observed, “the ultimate good desired is better reached by free trade in ideas,” for “the best test of truth is the power of the thought to get itself accepted in the competition of the market,” and “truth is the only ground upon which [peoples’] wishes can safely be carried out.” This is not to say that the Constitution compels the States to accept detailing without criticism and even regulation. To the contrary, if they oppose the practice, the Constitution encourages them to devote their considerable resources to loudly voicing that opposition and debating ways to regulate its supposed abuses – but not to silencing the free flow of truthful information that these new and dangerous laws target.’

Thus, the physicians of ACRE – clinical researchers and educators – strongly encourage the legislature in Minnesota to let physicians engage in clinical research and education in collaboration with the academic medical centers, but also our pharmaceutical and biotechnology partners. We respectfully submit that the excellent health care in Minnesota now is the result of this collaborative effort in years past. Legislative interference with any aspect of the physician-industry working relationship, especially that which hinders the free exchange of information, directly leads to patient harm.

Respectfully submitted on behalf of ACRE,

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NOTE:

The Association of Clinical Researchers and Educators (ACRE) is an organization of physicians who have dedicated their careers to excellence in clinical research and education, for the benefit of medicine and our patients. The physicians of ACRE have first-hand experience with all aspects of clinical research and education, and the steps necessary to translate them into the tools that physicians use to help their patients. ACRE wishes to be a resource for any and all Minnesota legislators.