On Your Behalf …

Legislative and Practice Affairs Division

No Free Dinner, No More Pens: New Pharma Ethics Rules Affect Professionals, Programs

By David E. Willett, Esq., CSA Legal Counsel

The Pharmaceutical Research and Manufacturers of America, PhRMA, has promulgated new rules of ethics that members are expected to observe. The rules are not laws. However, they were adopted by PhRMA to head off Congressional interest in enacting laws restricting pharmaceutical company marketing to professionals.

The new rules have two components. Gifts are eliminated or restricted. Additionally, new conditions are placed on support for continuing medical education activities. Although the new rules have been criticized as inadequate to preclude some abuses that critics of the industry have claimed exist, they will cause changes in dealings with drug companies by both professionals and professional associations.

Manufacturers must not provide restaurant meals to health care professionals. “Modest occasional meals” are permitted in the setting of a hospital or physician’s office when incidental to education or informational exchange. Offering “take out” meals to be eaten without a company representative being present is inappropriate. Inclusion of spouses or guests of professionals is also deemed inappropriate. Gifts of tickets or items for entertainment or recreational use are banned.

Non-educational gifts, even if practice-related, are banned. The ubiquitous ballpoint pens and markers are now collectors’ items, as are note pads, clip-boards, and coffee cups. Token consulting or advisory arrangements, intended to compensate professionals for the cost of attending professional meetings, are not appropriate. Bona fide consulting arrangements are permitted, subject to specific criteria.

Financial support from companies is permissible for scientific and educational conferences dedicated primarily, in both time and effort, to promoting objective scientific and educational activities and discourse. One or more educational
presentations should be the highlight of the gathering, and the main incentive for bringing attendees together.

Pharmaceutical company support for continuing medical education should be separated by the company from sales activities. Support should be given to the CME provider, not to participants, and should not be used to promote a particular medicine or course of treatment. Responsibility for course content, selection of participants, and such matters rests with the organizers of the conference, and their independent judgment and ACCME standards are to be respected. A company should not provide meals directly at CME events, except that the company, at its own discretion, may provide the financial support expended by the organizers to provide meals for all participants.

The revised code imposes requirements upon manufacturers for the training of representatives. It also requires companies to attest to their compliance at various times. Separate provisions address direct arrangements between manufacturers and individual professionals for their services. The revised Ethics Code will engender some changes in professional support by pharmaceutical manufacturers that are beyond the disappearance of free pens.

Charles A. O’Brien, Esquire:
In Memoriam

By William E. Barnaby, Esq., CSA Legislative Counsel

Even though a medical malpractice storm swept through many states in recent years, California physicians remained protected by MICRA, the landmark Medical Injury Compensation Reform Act of 1975.

Charles A. O’Brien was one of the chief architects of MICRA. Perhaps even more important, his unique political know-how figured importantly in convincing then-Governor Edmund G. (“Jerry”) Brown, Jr., to sign the novel legislation into law. In the ensuing years, California physicians and their patients have benefited greatly from readily available and affordable malpractice coverage, as well as the improved patient access to care it has enabled.

As a young San Francisco lawyer, he impressed then-California Attorney General Edmund G. (“Pat”) Brown. A few years later, O’Brien served as Governor Pat Brown’s top aide, then called Executive Secretary. His
effectiveness in that role not only proved his political skills to Governor Pat Brown but made them familiar to Pat’s son, Jerry, when he was elected Governor in 1974.

In 1975, California healthcare was in turmoil. The medical malpractice crisis had produced yearly liability premium increases to the tune of 400 percent and physicians were avoiding risks in their practices or leaving the state. A Physicians Crisis Committee was formed to add another aggressive force to work with the California Medical Association (CMA) and the California Hospital Association (CHA) toward an urgent solution.

A watershed was reached when many California physicians, particularly anesthesiologists, resorted to a strike—a refusal to perform elective surgeries—until the situation was remedied. The public was up in arms. They rightfully feared that access to medical care was in jeopardy.

The Physicians Crisis Committee selected Charles O’Brien as their counsel, both for his political clout and the legal acumen demonstrated during nearly 10 years as California’s Chief Deputy Attorney General. A tumultuous special legislative session produced MICRA in the form of AB 1XX, authored by Democratic Assembly Health Committee Chairman Barry Keene. Final passage was on a bipartisan vote over the opposition of Democratic Assembly Speaker Leo T. McCarthy, who wanted the bill sent to a conference committee for additional refinement.

Tremendous pressure was brought to bear on the new Governor, Jerry Brown, to veto the bill. Damage limits, such as the $250,000 “cap” on non-economic damages in AB 1XX, were constitutionally suspect. The California Trial Lawyers Association held great sway in those days and they had friends in high Administration office. In that heated milieu, the credibility of Charles O’Brien with Gov. Jerry Brown stood the pro-MICRA coalition in good stead. Brown signed MICRA into law, an action he proudly cites to this day.

Even with the new groundbreaking law in place, California physicians still had not gained the relief needed. Most commercial insurers had either dropped professional medical liability coverage or left the state altogether. Going “bare” or without liability protection and leaving their personal assets totally at risk was not a viable option for most doctors. Out of necessity, four physician-owned medical malpractice insurance companies were formed. Three were closely affiliated with county medical societies. The other, The Doctors Company (TDC), was an independent carrier that offered coverage statewide. Charles O’Brien was one of TDC’s founders and served as its general counsel and a member of its Board of Governors until he retired in 2004.
Whenever a threat to MICRA arose, he was on the scene and actively engaged. He was a shrewd analyst of political developments and politicians. He was widely respected within the insurance industry. He was active in state and national political and regulatory affairs. He was a wonderful storyteller in the finest tradition of an Irish politician. He was a force to be reckoned with.

California’s political history might have taken a different course had the 1970 general election turned out differently. As the Democratic candidate for California Attorney General, O’Brien lost by 18,200 votes out of 6.2 million to Evelle Younger at the same time that Governor Ronald Reagan was re-elected to a second term. On occasion, he mused about how rainy weather in Alameda County and sunshine in Orange County might have altered the election outcome and the course of California politics.

During his last few years, O’Brien suffered the effects of the trench foot he contracted in the World War II Battle of the Bulge, where he fought as a machine gunner in the infantry. As the U.S. Army battled to victory in Europe, he helped liberate Nazi concentration camps.

His reverence for personal liberties and the American political process, and his respect for his fellow men and women, were based on his real-life experiences as well as his magna cum laude degrees from Harvard.

Charles O’Brien died in his sleep at age 83 in his Danville home on September 3, 2008. Less than a month earlier, another key MICRA architect passed away—James E. Ludlam, longtime counsel to the CHA. The other principal MICRA writer, Howard “Hap” Hassard, the legendary CMA General Counsel and founder of the prestigious Hassard, Bonnington et al. law firm, died in 1992. His colleague and MICRA collaborator, David Willett, is CSA’s Legal Counsel. The O’Brien-Ludlam-Hassard triumvirate had the attentive ear of Governor Jerry Brown throughout the MICRA battle, according to Sacramento attorney Fred Hiestand, who then served as the Governor’s main liaison on the issue.

A deep debt of gratitude is owed by past and present California physicians, as well as the general public, for the pioneering efforts of these individuals who helped protect access to medical care.

It was our good fortune to work with and to have been befriended by Charlie over the past 30 years. It was a treat to be in his company and to learn from his insights. In more recent years, it was wonderful for both my son and me to enjoy the same relationship with his son and law partner, Devin, who continues to champion MICRA and provide wise counsel to TDC. Charlie also was survived by his wife of 54 years, Marie, son Brennan, and daughter Erin. His
family was his proudest and most enduring accomplishment which animated and sustained his love of law and life.

Inscribed atop the neo-classical façade of the Library and Courts Building near the California State Capitol is the prayerful quotation of American poet Sam Walter Foss: “Bring Me Men to Match My Mountains.”

Charles A. O’Brien was such a man.

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**Committee Appointments**

Active and resident members who are interested in becoming more involved in the CSA and would like to start by serving on a committee need to contact Linda B. Hertzberg, M.D., President-Elect, at lhertzberg@comcast.net or the CSA office at 800-345-3691 or csa@csahq.org by February 1, 2009, indicating interest in the following divisions and committees. For more information about the committees and the two divisions, call the CSA office or refer to the CSA Bylaws at [http://www.csahq.org/pdf/csa_bylaws.pdf](http://www.csahq.org/pdf/csa_bylaws.pdf).

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- Educational Programs Division
- Legislative and Practice Affairs Division

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- Committee on Peer Review
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