

## Business and research

To the Editor:

In the outstanding Special Article “Association of Funding and Findings of Pharmaceutical Research at a Meeting of a Medical Professional Society” by Drs. Finucane and Boulton, the explanations for potential bias in outcomes favoring pharmaceutical products when research was sponsored by the pharmaceutical industry did not include one seemingly obvious bias.<sup>1</sup> While less nefarious, it seems almost intuitive that the pharmaceutical industry would invest, like any other business, in studies that are most likely to have significant findings that favor their products.

This explanation is far different from “. . . supporting biased study designs . . .” or “. . . controlling access to, and analysis of, study data . . .,” as elaborated upon in the authors’ “Discussion” section. Preliminary information that indicates a benefit of a medication, either comparatively speaking or as a new finding, would be understandably pursued by the industry. So too, early information that disfavors a formulation may lead to abandonment without further investigation, simply as a cost-effective business decision. Thus, if a company is successful, most often the research and development dollars for legitimate studies will also be consistent with preliminary data that favor the investment into additional, well-designed trials in the first place.

There are, of course, examples in which investigation that clearly focuses on safety is done by industry even though there is little benefit to be gained from a financial perspective. The most recent, and now perhaps most well known, example is the Merck trial of long-term rofecoxib use for prevention of adenomatous polyps, which included as part of its initial study design a safety component assessing cardiovascular risk. This arm was included despite the lack of financial incentive to do so, ie, regardless of the findings, the data would not have been beneficial in promotion of the drug. A negative study would have been dismissed by many as a pharmaceutical industry-sponsored trial of inadequate design or sample size (or as suspect of data suppression, as evidenced by the “Discussion” section of this Special Article). A positive study would, as is now indisputable, have devastating corporate consequences, not only on the drug sales, but on the company portfolio overall.

F. Michael Gloth III, MD, FACP, AGSF  
*Johns Hopkins University School of Medicine*  
*Victory Springs Senior Health Associates*  
*Baltimore, Maryland*

doi:10.1016/j.amjmed.2005.01.023

## Reference

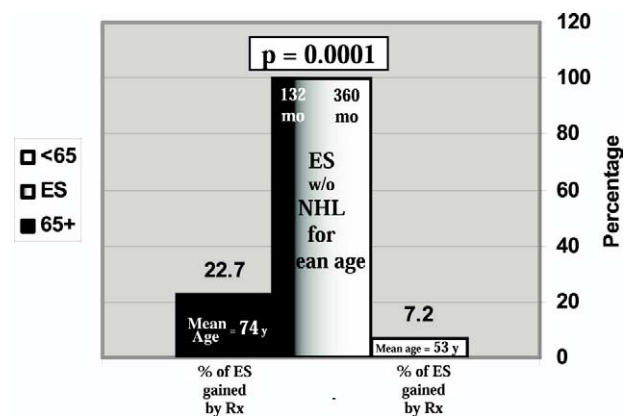
1. Finucane T, Boulton C. Association of funding and findings of pharmaceutical research at a meeting of a medical professional society. *Am J Med* 2004;117:842–845.

## Age-adjusted survival gained by treatment: An alternative way of presenting survival

To the Editor:

Survival of patients treated for non-Hodgkin’s lymphoma (NHL), as well as many other malignant diseases, is age dependent.<sup>1</sup> Current series calculate actuarial and estimated patient’s survival in absolute terms, either in time units (eg, months) or as percent of patients surviving (eg, 5 years’ survival).<sup>2</sup> We propose a new alternative method to determine and present survival data. Our method relates the survival of treated patients to the expected survival of untreated patients and to that of the patient’s own age group in the studied population.

For example, we retrieved and analyzed the data on 52 patients with aggressive NHL treated at our center. Median follow-up time was 34 months. To compare survival of older ( $\geq 65$  years;  $n = 28$ ) vs. younger ( $< 65$  years;  $n = 24$ ) patients, we first calculated the mean age in both groups ( $74 \pm 6.4$  and  $53 \pm 9.4$  years, respectively) and determined the mean survival in each group. We next subtracted from it the expected survival of untreated patients (an approximation for aggressive NHL—6 months). The value obtained can be termed Survival Gain achieved by Treatment (SGT). We obtained the data on the life expectancy of men and women in the general population in Israel for the mean ages of the study (Age-Adjusted expected Survival, AAS) from the Government Statistics Bureau. The proportion of AAS restored by treating NHL may be calculated by the formula: (SGT divided by AAS)  $\times 100\%$ . The results for our patient groups are presented in the Figure. The advantage obtained by treatment for each age group of patients is clearly portrayed by this method. A highly significant finding that emerges is that treating NHL in elderly patients ( $\geq 65$ ) restores a proportion of age-adjusted “ideal” survival almost 3 times larger than for the younger age group. This method of analysis of survival data provides an alternative way to evaluate, present, and appreciate age-related results in treating NHL and other diseases.



**Figure** Proportion of age-adjusted expected survival (ES) gained by treating aggressive NHL: “old” vs. “young.”