

Ronald J. Podraza
6770 Windward Hills Drive
Brecksville, OH 44141
ronpodraza@juno.com

November 11, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004S-0233
Stimulating Innovation in Medical Technologies

Ladies and Gentlemen:

The biggest problem getting innovative medical device technologies “to the bedside” is the difficult, uncertain and newly expensive process of securing Medicare coverage, either locally or nationally, for procedures utilizing new technologies. The coverage process is becoming nearly insurmountable for all but the largest companies (most device innovators are quite small) due to increasingly demanding and confusing coverage requirements related to CMS’ application of Evidence-Based Medicine (EBM.)

In principle, EBM is a compelling basis for coverage decisions and indeed for decisions re the management and treatment of individual patients. The clinical caregivers, the patients and loved ones, and the payers all benefit from knowing what diagnostic and treatment methods will likely improve the health outcomes of patients with specific symptoms and histories.

In practice, however, CMS’ application of EBM is fraught with problems which I will identify in the context of my recommendations below.

I believe there are five steps HHS could take to stimulate innovation in medical technologies:

1. Apply EBM standards evenly and equally to existing medical practices and innovative medical practices. CMS now subjects innovative practices to EBM standards to which many existing methods have never been subjected and which they could not meet. This delays Medicare beneficiary access to promising new methods and restricts the beneficiaries to methods that have never been scrutinized using EBM methods. CMS has not meaningfully applied EBM methods to the vast majority of what it pays for, but

insists upon utilizing EBM methods for anything new, thus delaying or blocking innovation in clinical practice.

2. Use total cost to Medicare as the basis for prioritizing the EBM review priorities of medical procedures new and old. CMS describes itself as a fiduciary of Medicare funds. Fiduciary principles would dictate that the fiduciary first address *big budget categories (big usage of dollars)* as opposed to the *new methods*. A fiduciary's priority would be to examine the big things first.
3. Differentiate between high cost innovations and others. For the others, recognize that FDA's scrutiny of new technology-based procedures generates considerable information about the medical utility of a procedure. CMS' statements that FDA only determines how and why a treatment works and not whether it is a desirable treatment for certain patients is disingenuous. More is known about the clinical utility of new technology-based procedures scrutinized by FDA than is known about most of what Medicare currently pays for. Until a procedure based on a new technology also becomes a big drain on dollars, HHS' EBM review resources are better deployed elsewhere than on new low- and moderate-cost procedures which have been scrutinized by FDA.

Also recognize that most innovations are not high cost to the Medicare program initially. It takes years to disseminate new technologies and new procedures.

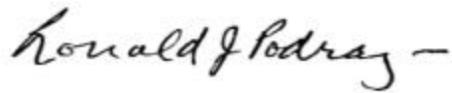
4. Eliminate the negative consequences to the innovators of academic disagreements among experts in the EBM process. Many innovators have made expensive, good faith efforts to meet EBM standards, only to find that CMS or its contracted experts disagreed with the outcomes studied by the innovators and/or the design of the study itself. Any two clinical study designers can find fault with each other's study designs. Any two health policy makers can find fault with the outcomes each other chooses as most important to study. Innovators must have some certainty that well designed studies looking at meaningful outcomes will not be dismissed by MCAC, Technology Assessment contractors, or CMS officials. One possible method for doing this is to certify study designers and to prohibit CMS and its contracted experts from dismissing the study of a certified designer on the grounds of "wrong outcomes" or "design flaws."
5. Clarify the scope of discretion of contractor Medical Directors to cover a clinical trial authorized by the FDA. The point of the 1995 interagency memorandum was to allow Medicare beneficiaries to participate in FDA-authorized clinical trials. Nevertheless, there are contractor Medical Directors refusing coverage for IDE trials on the basis that the IDE study designs, deemed adequate by FDA, do not meet the Medical Directors' interpretation of well-designed studies. Is it the intent of HHS to exclude patients from potentially beneficial treatments while sister agencies contend over study designs?

American health care became the standard for the world long before CMS began applying its version of EBM to the coverage process. Innovation has flourished because there was a receptive market for it. Now, however, the biggest U.S. purchaser of health care, Medicare, is

telling the community of innovators that Medicare will subject their innovations to a high and uncertain level of scrutiny while freely purchasing everything else without any EBM review.

I submit that this discouragement of innovation would not be necessary if CMS reviewed its big dollar drains first (many of which are low-technology or no-technology procedures) and discontinued coverage for those lacking the evidence to support their continued usage. Enough dollars would be freed up to pay for the relatively small percentage of the Medicare budget going towards most new technologies. Treat new technologies as expensive only when they truly are becoming so.

Yours sincerely,

A handwritten signature in cursive script that reads "Ronald J. Podraza" followed by a horizontal line.

Ronald J. Podraza