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The Authors Respond

Dear Editor,

We appreciate Dr. Rich's careful review of our manuscript, which appeared in the March/April 2003 issue of *JMCP*.¹

As we clearly outlined in the introduction, our objective was to suggest a method for using administrative claims to evaluate potential direct population costs of pipeline therapies prior to the availability of full cost-effectiveness analyses. This analysis was undertaken before the launch of the product in order to provide preliminary information to those with direct responsibility for the pharmacy budget alone. The study was published after the drug was approved.

The majority of Dr. Rich's points (points 1, 2, 4, and 5) focus on costs related to clinical outcomes, side effects, and patient functioning that would be included in a full cost-effectiveness or budget impact analyses. These types of analyses are critically important to evaluate the true value of therapies, but formulary dossiers containing the information may not be available until after the drug is marketed.² However, payers frequently require customized proactive information prior to marketing to anticipate potential blockbuster drugs and possible cost-containment strategies. The proposed claims analysis is an attempt to bridge that early information gap.

When more information becomes available through detailed cost-effectiveness and completed phase III and IV studies, the true budget impact on both the pharmacy and medical budgets would indeed take precedent over preliminary assessments. For instance, the 63-week extension of the EVIDENCE study demonstrated a 17% reduction in relapse rates for 44 µg tiw interferon beta-1a (Rebif-IB1a2) compared to 36 µg cw interferon beta-1a (Avonex-IB1a1), indicating a sustained impact on relapse over time.³ With regard to side-effect management, a statistically significant higher rate of flu-like symptoms were also reported in the IB1a1 group (53.4%) compared to the IB1a2 group (44.8%).³ Information from the trial shows that neutralizing antibodies are not related to clinical impact on relapse rates; therefore, the influence of neutralizing antibodies is still unclear.³

We did include administrative costs of prior authorization related to costs that plans may incur by implementing a prior-authorization program (point 3). We assumed in the base analysis that the new product would compete with existing therapies and IB1a2 would be used in place of other similar products. The model is flexible to incorporate a variety of scenarios, but we chose a share-shift analysis approach in the base case where there was some decline from the other products.

The 80% share estimate in new users was indeed aggressively set forth by the manufacturer (point 6). We specifically performed sensitivity analysis around this estimate as presented

in the manuscript. However, a reduced market-share estimate would only reduce the anticipated impact of interferon beta-1b.

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■ Patient-Reported Utilization Patterns of Narcotic Drugs

Dear Editor,

I read the article on the above subject in the May/June 2003 issue of *JMCP*¹ with interest. A perhaps far more interesting topic could be explored by the authors: the topic of "the rest of the story," when patients choose to take themselves off of such medications. In the treatment of chronic nonmalignant pain, it is important to recognize that this category is a hodge-podge. We cannot assume that there is only one situation or pathophysiology involved. So, any commentary on the "group" needs to recognize that there will be variation in applicability.

However, with that said, it is fascinating to observe the patients with "chronic nonmalignant pain" who become fed up with taking all the pills (or patches) and simply take themselves off. They may go from high doses of very expensive medications to use of nothing more than ibuprofen. Yet, this may occur with no observable change in the underlying condition. The only thing that changes is their desires. This is a very, very revealing outcome when it happens.

Perhaps these authors would care to look at "the rest of the story." They must certainly have some patients who eventually go off of all the narcotics. When this happens, what leads to the outcome? What evidence exists that underlying pathology changed? Or is the change simply one of choice? If so, what do we learn from this?

Obviously, there are many countries in the world that do not

have the economic situation to support the use of chronic high-grade narcotics (particularly very expensive ones). What do their citizens do? And have you ever seen an animal that needed chronic narcotics? The lessons I'm obviously implying are easily available for anyone who simply wishes to look at pain behavior across the world. However, ethnocentrism seems to lead many investigators to turn a blind eye to the rest of the world.

While full understanding of pain behavior in humans requires looking at all humans, we may still learn a great deal from examination of selected subgroups. In regard to the subgroup of patients with chronic nonmalignant pain, there is much to learn about pain from an examination of desires.

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Common Industry Practices and OIG Compliance Guidance

Dear Editor,

I read the Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers published May 5, 2003.¹ In my opinion, the key to the "guide" is contained in the introductory discussion under kickbacks. The OIG states that what people may regard as common industry practices (for example, relationship-building activities such as

taking customers to entertainment or sporting events, dinners, or seminars) are not necessarily legal when viewed under the antikickback laws. This is a somewhat disingenuous statement, as there is a lot of discretion involved in determining these matters, and it is a very technical reading of a very vague statute.

The antikickback statute is so broadly written, *everything* seems illegal. We've raised, and now seem to celebrate with large legal fees, a generation of technocrats: compliance experts that sanctimoniously opine on what's legal, etc., based on literal readings, without understanding or caring about the impact from a substantive or industry standpoint.

The biggest trap in the guidelines is the reliance on the so-called "one purpose" test: If one purpose of a program can be considered to be inducing referrals, then the whole program structure fails. What is it that the drug manufacturers do that isn't based on the motivation to sell their product or induce referrals? Does anyone think the education and research programs, even divorced from sales, are charitable? If the OIG wants price competition, it seems to me that it should try to adapt its rules to common industry practices and focus on obvious abuses and outright fraud or inappropriate conduct. Doesn't price competition require manufacturers to follow, not disregard, "common industry practices?"

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