

## Matching Risks to Interventions: When to Treat, How to Treat

An interview with Richard C. Pasternak, MD; Associate Professor of Medicine, Department of Medicine, Harvard Medical School, Boston, MA

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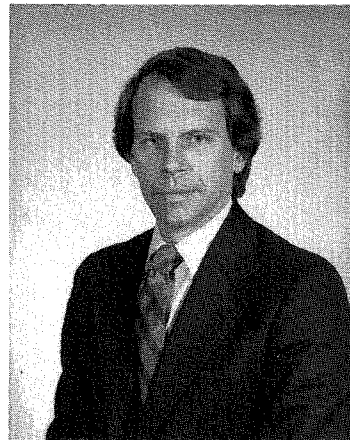
### ... INTRODUCTION ...

Dr. Richard C. Pasternak is an internationally recognized expert on lipid management. One of the investigators in the Cholesterol and Recurrent Events (CARE) study, Dr. Pasternak has also been involved in other high-profile research projects, including the Harvard Atherosclerosis Reversibility Project Research Group (HARP) and the cardiac component of the multicenter Study of Women Across the Nation (SWAN). He was recently appointed to the Coordinating Committee of the National Cholesterol Education Program (NCEP), which issues perhaps the most highly regarded and observed clinical guidelines for the treatment and prevention of high serum cholesterol in adults.

A graduate of Yale University, where he earned both his MD and BA degrees, Dr. Pasternak served his residency at Massachusetts General Hospital in Boston. He went on to fulfill a fellowship in clinical cardiology and research at Massachusetts General Hospital. Dr. Pasternak also serves on several editorial boards for peer-reviewed cardiology journals and has authored or contributed to more than 110 articles, abstracts, monographs, and other publications.

### When to Treat

**AJMC:** *There seems to be a lot of debate about when a patient should be treated for elevated LDL cholesterol levels. Opinions as to when a statin or other lipid-lowering agent should be introduced varies widely. When do you recommend a statin (or other lipid-lowering therapy) be introduced?*



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**Richard C. Pasternak, MD**  
Associate Professor of Medicine  
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**Dr. Pasternak:** My approach is pretty conventional in that I'm right in line with what the experts recommend. Of course, I'm a little biased because I'm a member of the NCEP Coordinating Committee. Some would say that makes me an "evangelist" instead of a "snail" with regard to using lipid-lowering agents. But it's not like religion—there's a substantial amount of science behind what the NCEP consensus panel recommends with regard to who should be treated, when to treat them, and what goal to treat them to. *[Editor's Note: NCEP Guidelines recommend starting drug therapy after an adequate trial of diet and exercise if a patient: (1) has an LDL-C (low-density lipoprotein cholesterol) of 190 mg/dL*

*or higher and fewer than two coronary heart disease (CHD) risk factors, with the goal being 160 mg/dL; or (2) an LDL-C of 160 mg/dL or higher and two or more CHD risk factors, with the goal being 130 mg/dL; and (3) an LDL-C of 130 mg/dL for patients with CHD with the goal being 100 mg/dL.]*

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First of all, we have to remember we're treating LDL cholesterol, not total cholesterol. The total cholesterol numbers are just a way to get at who has an elevated LDL cholesterol level. I think that's a common mistake that both the public and some algorithm writers make—they focus too much on total cholesterol and not enough on LDL cholesterol. If an individual has multiple risk factors, I'd consider drug therapy if the LDL cholesterol is over 160 and would try to get the LDL to under 130. If the patient has vascular disease, coronary or otherwise, then I'd consider drug therapy if the LDL is over 130 and I'd try to get it to 100. In short I follow the NCEP guidelines pretty closely with respect to initiation of therapy. The NCEP basically recognizes three separate treatment thresholds. These are: the patient with the coronary disease, the patient with multiple risk factors, and the patient with no risk factors.

***AJMC: What are some of those risk factors?***

***Dr. Pasternak:*** The NCEP defines risk factors as: smoking; hypertension; low HDL (high-density lipoprotein) chole-

sterol (35 mg/dL or lower for men, 45 mg/dL or lower for women); being a male over 45; being a female over 55, or a younger woman who has experienced premature menopause and isn't on estrogen replacement therapy; and finally, having a family history of premature heart disease.

***AJMC: You don't think physicians should wait for a cardiovascular event to begin prescribing lipid-lowering drugs?***

***Dr. Pasternak:*** Absolutely not! One reason is that it's now clear that treating elevated LDL cholesterol can *prevent* cardiovascular events. The thinking that says you shouldn't give patients cholesterol-lowering drugs until an event occurs is less and less common. It's certainly not a cost effective attitude. In our market, we're beginning to see that payers are looking at risk factor treatment. They're now interested in identifying multiple risk factor individuals and treating them to prevent cardiovascular events and the need for costly procedures.

#### Undertreating

***AJMC: Several studies say that only 25% of Americans who could benefit from lipid-lowering agents are actually receiving them. Fewer still are being targeted to NCEP guidelines. Why do you think this is?***

***Dr. Pasternak:*** That's absolutely true. Not enough prescriptions are being handed to patients. Once patients have the prescription, not enough of them are being filled. After they're filled, not enough of them are being refilled. And even if they are refilled, not enough of the medications are being taken. At every single step of the way there's drop-off. But the drop-off isn't due to any single problem.

I think the challenge now—and an important area for clinical investigators

to move into—is to answer the question of *why* we seem to be doing such a poor job of delivering therapy in clinical practice. Unfortunately, trial results do not always translate into patient practice results. Patients in clinical trials are followed very carefully and very regularly, usually by trained nurses as well as by physicians and there is a compelling interest in having everyone participate fully. Because of that, compliance and adherence is very good in clinical trials. But this hasn't been the case in clinical practice because the practicing clinician virtually never has the kinds of systems for delivery of care and compliance reinforcement that are available in a clinical trial.

There are other important issues. Cost is an issue, even if the patient has insurance coverage. And communication is an important issue. As with hypertension, patients who have elevated LDL cholesterol levels generally feel well and they rarely feel better when you treat their lipid abnormality. It is axiomatic in medicine that when you give a therapy to treat something that doesn't have any symptoms, it's much harder to convince patients that it's important to adhere to the therapy. I think that's an education and communication concern. Physicians and medical support people need to do a better job in educating patients about how important it is to take preventive therapy, even though it won't necessarily make them feel well.

For the most part, I think the problem is largely a systems issue. Clinicians simply don't have the kinds of systems available to make sure all the patients who need lipid-lowering therapies get them and actually take them.

**AJMC:** *What could be done to address that? What kind of "system" might work?*

**Dr. Pasternak:** There are several models but one of the most successful I've seen and am intrigued by is a disease management model known as MULTI-

FIT [Multiple Risk Factor Intervention in Post-Myocardial Infarction], which is a program that has been developed at Stanford University that is physician supervised, but nurse managed.<sup>1</sup> It is a triangular communication effort facilitated by a friendly computer system that keeps patient data and makes it available to the nurses who communicate directly with the patient, usually over the phone. Treatment in large part adheres to standardized algorithms and when questions arise, they go back to either to the referring physician or to one of the program's supervising physicians. I think that kind of model is one we'll see adapted and tailored to the larger market. That would help a lot.

**AJMC:** *What role could managed care organizations (MCOs) play in developing a better "system" to help ensure that patients who need lipid-lowering therapies get them and use them?*

**Dr. Pasternak:** The kind of system I've described and others like it should appeal to MCOs because they are very cost effective. They are easier to implement in a managed care setup where you have doctors, nurses, and payers all working under one roof, so to speak, than they would be in the old fee-for-service system where everyone tends to operate independently and the payer is removed and distant.

The bottom line is, I don't think physicians should be by themselves in this effort. They aren't ideally suited to make a major impact on rates of patient education and compliance because it's often not in their training and the current time pressures simply don't allow for it.

#### Statin Selection

**AJMC:** *There appears to be a lot of confusion about what makes one statin clinically distinctive from another. What differences have been demonstrated in LDL lowering effectiveness?*

**Dr. Pasternak:** Really, none. I don't think there are any important clinical differences in the safety or tolerability of statins. There have been some attempts by marketing departments to

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differentiate products, but clinically they're about even. The main difference is in peak effectiveness. Simply put, fluvastatin in its largest recommended dose is the least effective and simvastatin at currently approved doses is the most effective. This can be important to a clinician in some scenarios. For instance, if you're faced with someone for whom you've decided to give a statin and that person's LDL-C is over 200 and he or she has coronary disease and you'd liked to target a 100 LDL-C goal, you're not going to reach that goal with any of the available agents but you'll get the closest with a full dose of simvastatin. You won't get near it with the full dose of fluvastatin. On the other hand, if you have someone who just needs say a 15% or 20% LDL-C lowering, then I think they're all equally good. The other major difference is in cost, which in this medical environment, is a valid consideration.

**AJMC:** *Does there appear to be much of a difference among the statins with regard to side effects?*

**Dr. Pasternak:** There doesn't seem to be any clear difference. I have found that sometimes switching from one agent to another will occasionally remove a side effect that the patient thinks he has. The fear of side effects

probably has been exaggerated, although I think in my practice I'm seeing that the fear of elevated cholesterol is far greater than the fear of side effects.

**AJMC:** *What about statins for people with other concomitant disorders?*

**Dr. Pasternak:** As a clinician, I don't see that there are any clinical groups who should be given one brand of a statin over another. That's not true, however, for other lipid lowering drugs. One obvious one is niacin. Niacin should be used very cautiously in patients who have diabetes or active peptic ulcer disease. I also would be very hesitant to use niacin in someone who has a difficult-to-deal-with gastrointestinal tract.

#### Cost-Effectiveness Concerns

**AJMC:** *Is it always reasonable to try the least expensive approach first, before putting a patient on a more expensive regimen?*

**Dr. Pasternak:** There's a lot to be said, in this environment, for controlling costs. Diet, which costs virtually nothing, should be tried first. Unfortunately, diet has been undersold. We need to tell people that diet *does* make a difference and get them to try that first. But for patients with cardiovascular disease or multiple risk factors, I wouldn't wait for diet for very long. The fact is, there are many patients who do need an adjunct to diet, and that's where cholesterol-lowering therapies come in.

Niacin, of course, is one of the least expensive alternatives. I've used niacin a lot and found that many patients will have complete effectiveness with it. But it's not for everyone. The clinician can be trained to distinguish the kinds of patients who will take niacin or from who will never take it. For those patients, the cheap drug is no good if they won't take it, but a more expensive drug for them may prevent a heart attack. In that case, the more expensive drug *is*

cost effective. That's the kind of thinking that needs go into whatever guidelines MCOs use in making their formulary decisions.

**AJMC:** *Some MCO formularies require clinicians to try the least expensive statin first, even if they aren't convinced it's the agent of choice. What would you say to that policy?*

**Dr. Pasternak:** Cost is a fair issue, but it can't be disconnected from the fact that there are varying levels of disease that need different treatments. If you have a patient who has vascular disease, who has been on a reasonable diet and still has an LDL-C of 200, fluvastatin will not lower the LDL cholesterol far enough by contemporary guidelines. It will never work—using fluvastatin would just be putting off effective therapy. Cost should be looked at in the context of cost per increment of lower LDL, not per pill. If a treatment is more costly but more effective per mg/dL of cholesterol lowered, then that treatment may actually be the more cost-effective choice.

The fact is, clinicians need to be better at comprehending these issues. The better clinicians become at understanding the issues of the cost counters, the better we will be at explaining the clinical realities so that the best solution for both can be derived. The medical economists need to understand the importance of clinical decisions and the physicians need to understand the importance of non-clinical decisions. Cost effectiveness should not be an "us versus them" issue. We are in fact all in this together so that patients can get better.

### Special Populations

**AJMC:** *You've done some work in researching cardiovascular disease and treatment in women. Should gender play a role in deciding when to treat a patient with a lipid-lowering agent? Should age?*

**Dr. Pasternak:** Physicians should no longer think in terms of gender or age, but in terms of risk and benefit. It is true that the premenopausal woman is at less risk. I would probably treat a premenopausal woman with a highly-elevated LDL cholesterol before I would treat a man of the same age but with a lower elevated LDL-C level. However, once you show me someone who already has coronary disease, I become gender- and age-blind.

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**AJMC:** *What is known about treating cholesterol in diabetic patients? Is it important to be aggressive in treating their lipid abnormalities?*

**Dr. Pasternak:** If anything, clinical data show it's more important even though it is harder to treat lipid abnormalities in patients who have diabetes. The primary abnormality in diabetic patients is usually high triglycerides in concert with low HDL cholesterol levels. So the focus has often been to try to treat the more marked abnormalities of high triglycerides and low HDL numbers. Although we don't have any primary data on the effectiveness of that approach, we do have some very interesting subgroup data from the 4S trial (Scandinavian Simvastatin Survival Study) in a diabetic subgroup. In that trial, the patients with diabetes—like everyone else in 4S—were given simvastatin or placebo. So the focus was LDL-C lowering, not triglycerides and HDL-C therapy. The benefit in terms of total mortality reduction was greater,

in fact it was almost doubled, for the diabetic subgroup than for the non-diabetic study population. My conclusion is that the theme that keeps recurring is that we know the most about LDL-C lowering and it is the most effective way to lower overall lipid risk, regardless of other factors that may be present.

**AJMC:** *Is it important to have the diabetes completely under control before beginning cholesterol-lowering treatment?*

**Dr. Pasternak:** The lipid abnormality is definitely easier to treat if the diabetes is under control. But we all have diabetes patients who for one reason or another have a disease state that's difficult to control. I think it would be a mistake to just throw our hands up and give up on the lipids just because the diabetes isn't controlled. Sure, ideally, we'd love to have the diabetes perfectly controlled because then the lipids would be easier to treat. But we shouldn't wait for that, particularly in the patient who already has vascular disease.

**AJMC:** *Should clinicians be aggressive about treating lipids in smokers?*

**Dr. Pasternak:** Absolutely. The only difference is we should try to get them to stop smoking. Not treating a smoker's lipid abnormality would be like not treating a smoker's pneumonia or a broken leg. Smoking is probably more powerful of a CHD risk factor than elevated LDL-C, but these risk factors are probably synergistic, not simply additive. So instead than saying—rather nihilistically—“let's not treat abnormal lipids in smokers because the smoking's going to get them anyway,” I would say just the opposite: that it's even *more* important to treat abnormal lipid levels in a smoker because that person's at much higher risk.

**AJMC:** *You participated in a study that showed a strong correlation be-*

*tween elevated LDL cholesterol and hypothyroidism. What are the implications of this research when you consider that perhaps 20% of American women suffer from some degree of hypothyroidism, according to the American Thyroid Association?*

**Dr. Pasternak:** In the study you refer to, we looked through a hospital database to determine the frequency of lipid abnormality in people with even mild degrees of hypothyroidism.<sup>2</sup> In general, patients with hypothyroid conditions have moderately higher LDL cholesterol levels. Some of the hardest-to-treat high-cholesterol patients are those who have undetected hypothyroidism. The hypothyroid condition produces resistance to conventional treatment. The message of our paper was that thyroid abnormalities often go undetected and undertreated. It's our experience that it's exceedingly important to treat thyroid abnormalities because even modest degrees of hypothyroidism, when treated, can improve the patient's cholesterol abnormalities. Not necessarily *will*, but *can*. It's been well known for years that there's a correlation between hypothyroid conditions and high cholesterol, but most think that's the case only for patients who are *severely* hypothyroid. Our study showed that even *mildly* hypothyroid patients have elevated LDL cholesterol.

#### Cholesterol Studies

**AJMC:** *There seem to be a lot of studies published and still ongoing on hypercholesterolemia. Although some are still unpublished, many findings are coming out. What conclusions can be drawn so far?*

**Dr. Pasternak:** That the NCEP guidelines are pretty good. That the more you lower LDL cholesterol in the higher-risk patient, the more benefit you will get. If you put together the three big recent clinical trials on LDL-C lowering—the CARE study, the WOSCOPS

(West Of Scotland Coronary Prevention Study Group) study, and 4S—it's clear that the bigger benefit is for the sicker patient and there's less of a benefit for those with lower LDL cholesterol levels. But there is benefit for all.

**AJMC:** *You were one of the principal investigators for the HARP project, which analyzed the role of plaques in CHD. What conclusions were made by the HARP Research Group?*

**Dr. Pasternak:** The HARP project was a coronary angiographic quantitative regression trial.<sup>3</sup> Our primary endpoint was to look at the interplay between plaque and luminal widening in coronary artery. We were interested in discovering whether or not aggressive lipid lowering would benefit patients with so-called "normal" cholesterol levels (baseline LDL-C of 135).

We found that in this group there was no significant change in lumen diameter, nor in the percent of stenosis. But the HARP results have been widely misinterpreted. Many people mistakenly said the HARP results showed that lipid lowering didn't work or that lipid lowering may not be necessary if you have a baseline LDL cholesterol of 137. Those weren't my conclusions at all. HARP, like so many other regression trials, found that there is uniformly a benefit to LDL cholesterol lowering, in terms of event reduction. However, our numbers were too small to be considered statistically significant.

HARP taught us some very important things about coronary disease—mainly that plaque regression does not necessarily translate into event reduction and that a high-risk individual is not necessarily the patient who has a tight coronary stenosis. A patient is at risk for an event because of an *unstable* plaque. And in fact, the majority of unstable plaques are found in arteries with a less serious stenosis range of 50% to 70%, not in those with high-grade narrowing. So making a tight stenosis less tight is not

necessarily going to reduce the risk of an event. The characteristics of a high-risk plaque include the fact that they're rich in lipids and have a thin cap on top of them and perhaps the fact that they are more prone to clot. All it takes to cause a cardiovascular event is for one lipid-rich plaque with a thin cap to rupture.

People with very high LDL-C levels have really fat, juicy, very lipid-rich plaques. People with lower lipid levels, as the patients in the HARP project were, probably have slightly less lipid-rich plaques so there is less plaque shrinkage. But you can make those plaques smaller, obviously, if you take the source of lipids away. By getting the LDL cholesterol down, plaques become less vulnerable—even if they don't all shrink—because they will be depleted of lipids, and because lowering LDL cholesterol also improves the endothelial function of the vessels.

**AJMC:** *What remains to be elucidated? What types of studies should be done in the future?*

**Dr. Pasternak:** It would be nice to have some more conclusive data about LDL-

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C lowering in the older person. Other areas that could benefit from additional study is CHD prevention in women and in different racial groups. However, although I'm a fan of evidence-based medicine, I don't think that the absence of a study in these areas means we shouldn't be aggressive in treating lipid abnormalities. One of my most re-

spected mentors often says "in the absence of good clinical data, use good clinical judgment." Sure I'd like to see more studies in other groups but I wouldn't put that as an exceedingly high priority when basically, we understand that the biology is very similar.

Where I do think more attention is needed is for lipid-lowering drugs that haven't been as heavily studied—niacin, for example. Niacin could probably be adapted and made to be more tolerable. I'd also like to see more studies on the clinical benefit of lowering triglycerides and raising HDL-C independently. There's a lot of talk about the value of that, but we don't have primary data.

... REFERENCES ...

1. Debusk RF, Houston-Miller N, Superko HR, et al. A case management system for coronary risk factor modification following acute myocardial infarction. *Ann Intern Med* 1994;120:721-729.
2. Oettgen P, Ginsburg GS, Horowitz GL, Pasternak RC. Frequency of hypothyroidism in adults with serum total cholesterol levels 200 mg/dL. *Am J Cardiol* 1994;73:955-957.
3. Sacks FM, Pasternak RC, Gibson CM, Rosner B, Stone PH. The Harvard Atherosclerosis Reversibility Project (HARP) group: Effect on coronary atherosclerosis of decrease in plasma cholesterol concentrations in normocholesterolemic patients. *Lancet* 1994;344:1182-1186.



**CME QUESTIONS: TEST #0397S1**

**Instructions**

After reading this Special Report, select the best answer to each of the following questions. In order to receive 1 CME credit, at least 7 of the 10 answers must be correct. Estimated time for this activity is one hour. CME credits are distributed on a yearly basis.

**1. New evidence shows unstable plaques may be more responsible for coronary events than arterial stenosis. The lesions most likely to rupture are:**

- a) those that are mildly to moderately stenotic with a lipid-rich core
- b) those that are large and severely stenotic
- c) those that adhere tightly to the lumen of the vessel
- d) none of the above
- e) all of the above

**2. According to NCEP (National Cholesterol Education Program) Guidelines, drug therapy should be initiated in patients who:**

- a) have coronary heart disease (CHD)
- b) have two or more risk factors for CHD
- c) have fewer than two risk factors for CHD but have a low-density lipoprotein cholesterol (LDL-C) level of 190 mg/dL
- d) all of the above
- e) none of the above

**3. Studies of cost effectiveness should consider not only direct costs, but also:**

- a) outcomes
- b) quality of life
- c) long-term drug acquisition charges
- d) a and b only
- e) a, b, and c

**4. Which of these lifestyle changes has *not* been shown to reduce atherosclerotic disease:**

- a) losing weight
- b) exercising 4 to 5 times a week
- c) decreasing salt intake
- d) following a low-fat, low-cholesterol diet
- e) stopping smoking

**5. Angiotensin converting enzyme (ACE) inhibitor therapy for patients after MI with symptomatic or asymptomatic left ventricular dysfunction has been shown to:**

- a) reduce total mortality 19%
- b) reduce cardiovascular mortality by 40%
- c) increase the need for revascularization procedures
- d) be dangerous if started too soon after acute MI
- e) be vastly underutilized in ideal post-MI candidates

**6. Estrogen replacement therapy for postmenopausal women does not:**

- a) reduce LDL cholesterol
- b) reduce HDL cholesterol
- c) reduce recurrent cardiovascular events
- d) normalize the coronary endothelial response
- e) count as a cost-effective approach to reducing CHD in postmenopausal women

**7. Which has been shown to be both efficacious and cost effective as a primary prevention therapy for CHD:**

- a) acupuncture
- b) aspirin
- c) diuretics
- d) ACE inhibitors
- e) beta-blockers

(CME QUESTIONS CONTINUED ON S48)

<p><b>AMA/CME TEST FORM</b></p> <p>AJMC Test #0397S1</p> <p>Promoting Hypercholesterolemia Management in a Managed Care Environment</p> <p><i>Application for 1 Credit Hour of AMA Category I</i></p> <p>(Test valid through January 31, 1998. No credit will be given after this date.)</p>		<p>Please circle your answers:</p> <p>1. a b c d e</p> <p>2. a b c d e</p> <p>3. a b c d e</p> <p>4. a b c d e</p> <p>5. a b c d e</p> <p>6. a b c d e</p> <p>7. a b c d e</p> <p>8. a b c d e</p> <p>9. a b c d e</p> <p>10. a b c d e</p>	<p>(PLEASE PRINT CLEARLY)</p> <p>Name _____</p> <p>Address _____</p> <p>City _____</p> <p>State/Zip _____</p> <p>Phone # _____</p> <p>Please enclose a check for \$10, payable to American Medical Publishing, LLC, and mail with this form to:</p> <p><b>The AJMC CME Test</b>                  American Medical Publishing                  322-D Englishtown Road, Suite 101                  Old Bridge, NJ 08857</p>
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**CME QUESTIONS: TEST #0397S1**

(continued from page S47)

**8. According to the AHA's consensus panel, candidates for ACE inhibitor therapy include patients who:**

- a) are stable, but high-risk
- b) have had at least one previous MI
- c) show left ventricular dysfunction
- d) have symptoms of congestive heart failure
- e) all of the above

**9. AHA guidelines suggest estrogen therapy should be started in all:**

- a) postmenopausal women
- b) perimenopausal and postmenopausal women
- c) premenopausal women who are at high risk for CHD
- d) postmenopausal women with atherosclerosis
- e) perimenopausal and postmenopausal women who are at risk for CHD and osteoporosis

**10. Which has *not* been defined by the NCEP as a risk factor for CHD:**

- a) smoking
- b) hypertension
- c) having low HDL-C and high LDL-C levels
- d) being male over 45 or female over 55
- e) having a sedentary lifestyle

**PROGRAM EVALUATION**

Albert Einstein College of Medicine & Montefiore Medical Center would like to have your opinion. Please fill out the questionnaire below, tear off along the dotted line, and mail along with your AMA/CME test form. We thank you for your evaluation, which is most helpful.

*On the whole, how do you rate the information presented in the article?*

\_\_\_ excellent \_\_\_ good \_\_\_ fair \_\_\_ poor

*Is the information presented useful in your practice?*

\_\_\_ yes \_\_\_ no

Comments:

\_\_\_\_\_

*Do you have recommendations to improve this program?*

\_\_\_ yes \_\_\_ no

Comments:

\_\_\_\_\_

*Were any portions of this program unsatisfactory or inappropriate?*

\_\_\_ yes \_\_\_ no

If so, which?

\_\_\_\_\_

*Do you find the information presented in these articles to be fair, objective, and balanced?*

\_\_\_ yes \_\_\_ no

*Is there subject matter you would like included in the future?*

\_\_\_ yes \_\_\_ no

Comments:

\_\_\_\_\_

*In your opinion, were the authors biased in their discussion of any commercial product or service?*

\_\_\_ yes \_\_\_ no

Comments:

\_\_\_\_\_

Program Evaluation

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