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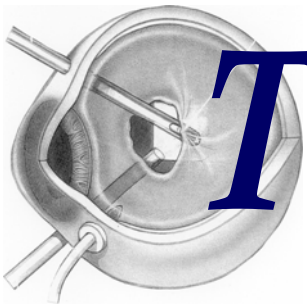


# The Light Pipe



The newsletter of Georgia Retina, P.C.

## What's Your Diagnosis?

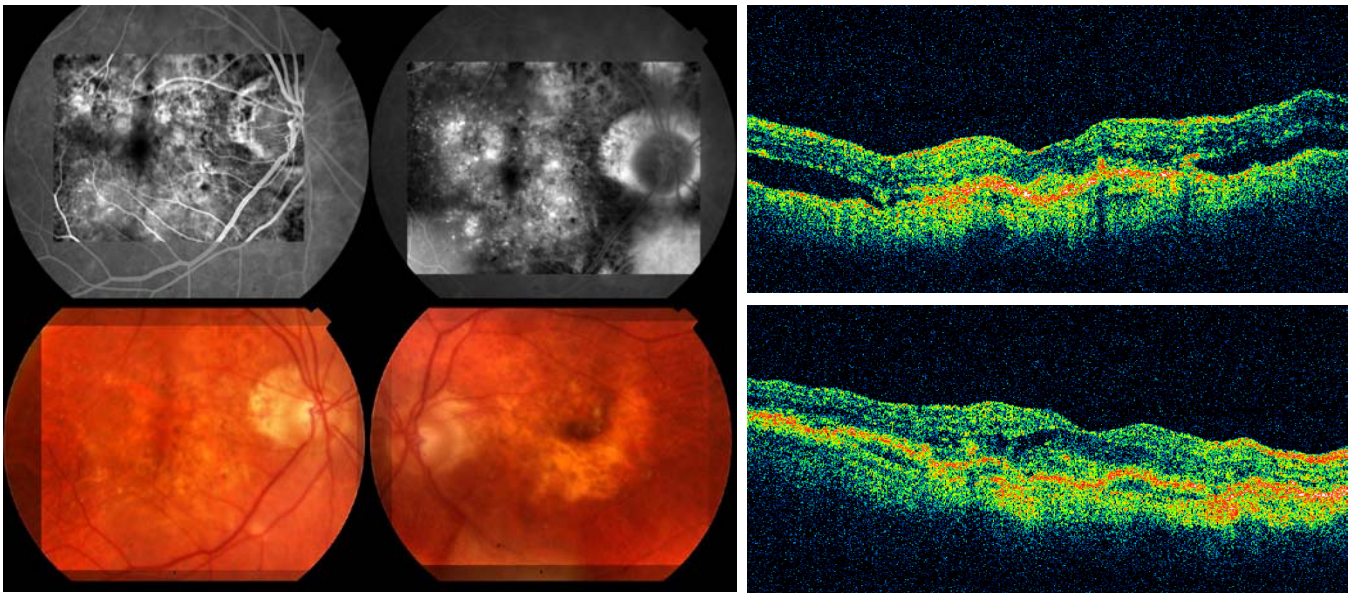
CASE STUDY: An 89-year old white man with hypertension, arrhythmia, atrial fibrillation for which he is on Coumadin, and osteoarthritis, demonstrating a progressive decline in vision of his right eye. He is on systemic anticoagulation. He lost central vision in his left eye from advancing macular degeneration and possibly an RPE tear.

He was seen on 11/16/06, with visual acuity of 20/100 +2. A fluorescein angiogram and OCT were performed (see images below). The fluorescein angiogram demonstrated increasing hyperfluorescence under the fovea of the right eye. The OCT demonstrated accumulation of subretinal fluid, some vague cystoid macular edema, loss of the foveal depression, and general thickening of the entire macular area.

*(Conclusion on page 2)*

**ALSO IN THIS ISSUE:**





***Diagnostic images from 11/16/06: Fundus photographs, fluorescein angiography and optical coherence tomography***

## Statins and AMD: Is There a Benefit for Our Patients?

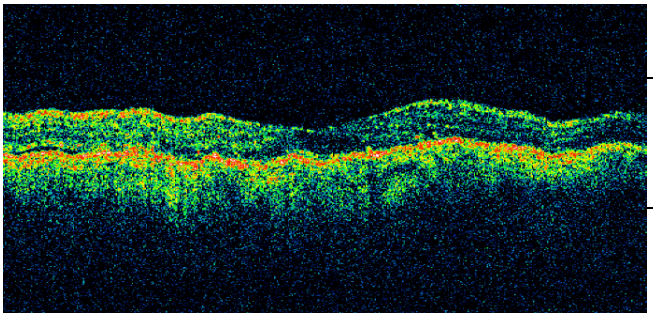
Age-related macular degeneration (AMD) is a progressive, degenerative disorder of the retina and is the leading cause of irreversible vision loss among older adults in the United States and industrialized countries. Until recently, most treatments only slowed the loss of visual function in later stages of wet AMD, but with the advent of newer agents, vision loss can be restored in a large percentage of patients. Nevertheless, there is still no effective treatment for arresting its progression in its earliest phases when only drusen and mild pigmentary changes are evident.

The Age-Related Eye Disease Study was a large randomized clinical trial which showed that long term oral supplementation with a high dose multivitamin supplement and/or zinc significantly reduced progression to advanced AMD in subjects in the highest risk categories (23% intervention versus 28% placebo). However, some 75% of people did not benefit. Therefore, the majority of subjects at risk will progress to advanced AMD and most of these will experience incapacitating vision loss.

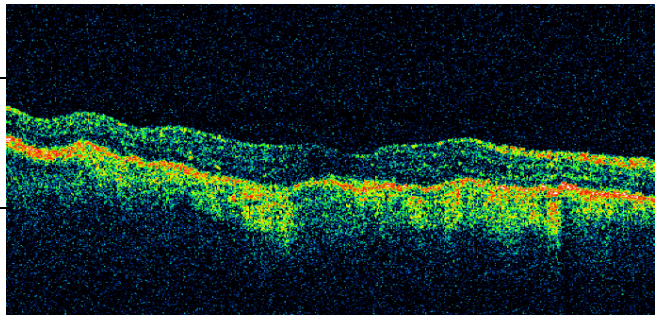
*(Continued on page 5)*

## What's Your Diagnosis? *continued from page 1*

We diagnosed subfoveal subretinal neovascular membrane, and an Avastin injection was performed. The patient returned 28 days later. Visual acuity had improved to 20/30 -2 at distance and 20/25 at near. *-MSJ*



***OCT images, followup visit 28 days later (12/14/06).***



## Sutureless Vitrectomy

As eye doctors we are trained to think small. That is, we pay attention to fine details that are otherwise unnoticed by casual observation. The same goes for our surgical techniques. In general, the smaller the incision or the fewer sutures, the better. We have seen this in cataract surgery where the evolution of clear corneal wounds and narrower incisions has transformed a procedure with a lengthy recovery time to one that can be performed through an incision less than 3mm long. Along with these advances patient expectations have also changed. Sutureless, topical procedures and multifocal intraocular lenses have elevated the expectations of what constitutes an acceptable result.

A similar evolution is occurring in vitreoretinal surgery where traditional vitrectomy techniques involve scleral incisions to accommodate 20 gauge instruments. In most cases these need to be closed with absorbable sutures as does the overlying conjuctiva. Twenty five (25) gauge instruments now available eliminate the need for conjunctival and scleral incisions by placing the scleral openings directly through the intact conjunctiva. Plastic trocars are used to make stab incisions for the light pipe, infusion and vitrector. At the conclusion of the case the trocars are removed and the incisions are generally self sealing. Innovative advances in 25 gauge surgical equipment along with the willingness of vitreoretinal surgeons to explore the application of this technology have lead to expanded indications for small gauge surgery.

In fact, some surgeons claim to have completely abandoned 20 gauge instruments altogether suggesting that 25 gauge surgery is faster, less invasive and leads to quicker visual recovery. This represents a minority of surgeons at this time but the applications of 25 gauge surgery are definitely expanding. For example, within our practice we have evolved from entirely 20 gauge surgery 18 months ago to currently approximately 70 % twenty five (25) gauge. Furthermore, patients that we considered poor candidates for sutureless vitrectomy last year have become more acceptable candidates as the instruments have improved and our ability to use them has improved as well. There are some limitations. The thinner instruments tend to be less rigid making peripheral dissection and visualization difficult. Similarly, the smaller bore of the vitrector may translate into longer vitrectomy times due to reduced flow. Illumination is also an issue through the smaller gauge light pipes practically requiring the purchase of special light sources for adequate visualization.

Twenty three gauge surgical instruments have been developed to address many of the limitations of the 25 gauge systems. These instruments address a major short coming of 25 gauge instruments which may be too flexible for bimanual instrumentation used in complex diabetes surgery and proliferative vitreoretinopathy. Twenty three (23) gauge instruments are far more rigid and behave more like the 20 gauge instruments with which we are comfortable. The obvious advantage is that bimanual manipulation is safer and easier with more rigid instruments and overall vitrectomy time may be shorter due to the increased diameter of the port compared to 25 gauge vitrectors. Some surgeons are suggesting that 23 gauge instruments may in fact replace the traditional equipment all together reserving a place for 25 gauge instruments for the simplest cases.

However, where does cost come into this discussion? With advancement comes increased cost. The instrument packs are more expensive and the disposable instruments are also more costly. The suppliers will argue that quicker procedures will lead to less time in the OR making us all more efficient and less costly. Have we seen this with cataract surgery? Are we headed for the 20 minute, sutureless, topical vitrectomy? In fact, using smaller gauge instruments can sometimes slow us down because of the increase in time it takes to remove the vitreous or remove a stubborn membrane. Thus far it is doubtful that any savings has been realized. In reality it has likely become more costly for hospitals to provide this service while threats of further cuts loom.

Nevertheless, either you do or do not believe in technology. It may be as simple as that. Thanks to innovative efforts by engineers and surgeons in our field we are constantly pushing the envelope. It is truly exciting to be an active part of this evolution even though we may ultimately be pricing ourselves right out of the operating room. *-MJR*

# Georgia Retina is Pleased to Welcome New Associate, Dr. Robert A. Stoltz

## Robert A. Stoltz, M.D., Ph.D.

Dr. Stoltz, a board-certified ophthalmologist, graduated from Union College with honors. He received a combined MD/PhD degree in medicine and pharmacology from New York Medical College. His ophthalmology residency at the University of Pennsylvania/Scheie Eye Institute was distinguished by his appointment as Chief Resident. Dr. Stoltz completed a two-year medical retina and vitreoretinal surgery fellowship at the University of Pennsylvania and then remained on faculty as Assistant Professor for three additional years. He also served as Chief of the Retina Service at the Philadelphia Veteran's Administration Medical Center. He has actively participated in numerous clinical and research trials, and was the Principal Investigator of the Fundus Photograph Reading Center involved with the Complications of Age-Related Macular Degeneration Prevention Trial (CAPT). Dr. Stoltz has published numerous articles on ocular pharmacology and ophthalmology in many prominent journals. Dr. Stoltz sees patients at our Douglasville, Marietta and Northside offices.

# Focus on Practice Management
# How Badly Will Medicare Cuts Harm You?

We've dodged another reimbursement bullet, at least to some extent. Instead of taking a full-on shot to reimbursements, the House of Medicine has absorbed a ricochet, if you will. In the 11th hour in December, 2006, the Congress stepped in to partly curtail proposed Medicare cuts for 2007. Though there are still cuts in '07, and though the cuts may be subtle to you, know that 2008 cuts portend a harsher reality; a reality where the bullet doesn't miss its target.

What's brought us to this point? Why the draconian cuts? Were you led to believe that the Medicare cuts had been put off for 2007? What does the future hold? How will these factors impact you, in your practice? Let's take a look.

### Genesis – What's brought us to this point?

As you know, Medicare compensates clinicians based on a formula derived in the late '80s and implemented beginning in 1992. Basically, Medicare (now the Centers for Medicare and Medicaid Services or CMS) assigned to the AMA's CPT* codes certain values looking at the "relative value" of the work effort (RVUw), practice expense (RVUpe), and malpractice expense (RVUmp) that each CPT entailed. Based on this methodology, a level 1 NP visit, for instance, would pay less than a level 3 NP visit because it required, theoretically, less work, less resources, and had lower med/mal exposure.

After Medicare assigned these values, they adjusted them by a geographic index (GPCI, geographic practice cost indices, cutely dubbed "Gypsies") which allowed for the cost differences to practice medicine in different areas of the country. For instance, it's more costly to practice medicine in New York City than it is to practice in Asheville, North Carolina and CMS contemplates this in their application of the GPCI.

The final touch to the fee calculation is the application of a Conversion Factor (CF) to the sum of these components which yields the fee the participating provider is paid for any given CPT code.

### Why we're here for 2007

Every 5 years CMS is legally obligated to revisit the "work values" (RVUw) that go into the CPT codes taking into consideration a variety of "work" factors that may have changed in procedures and the effort required to perform those services during the preceding five years. Additionally, for 2007, CMS looked at the practice expense methodology based on new data they'd obtained on the costs associated with the practice of medicine.

To make things more interesting, CMS is statutorily obligated to maintain "budget neutrality." That is to say, changes to RVU values are not allowed to cause aggregated program expenditures to increase too dramatically. So, to accomplish this control, CMS implemented a "budget neutrality adjustor" to its work RVUs for 2007. Let's look at how this works:

Fee calculation: [(RVUw x "budget neutrality adjustor" x GPCIw) + (RVUpe x GPCIpe) + (RVUmp x GPCImp)] x CF = 2007 FEE
Focusing on the metro-Atlanta fee for a level 3 new patient, we'll note the following:

*(Continued from page 3)*

RVUw = 1.34 (work)
"Budget neutrality adjustor" = .8994
RVUpe = 1.13 (practice expense)
RVUmp= .09 (malpractice component)

The GPCIs for each component are:
GPCIw = 1.01
GPCIpe = 1.089
GPCImp = .966

The national conversion factor for 2007 is 37.8975.

So when we plug those numbers into our formula we obtain a reimbursement rate for a level 3 NP office visit in the metro-Atlanta area of $96.07 as shown below.
[(1.34 x .8994 x 1.01) + (1.13 x 1.089) + (.09 x .966)] x 37.8975 = $96.07

## The cuts that *didn't* go away

Many medical societies explained to their membership that they'd experience cuts of at least 5% for 2007. That's fairly true. But what many didn't say is that most cuts would exceed 5%. Basically, many societies looked at the cut in the CF component of the calculation above, which was slated to be 5%. What some societies failed to go into depth about was that the cut in some work RVUs and practice expense RVUs could have led to even greater cuts for practices during 2007. In other words, though the CF for 2007 was not cut, some other cuts *did* go into effect.

## How will this impact your practice?

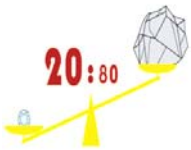
The answer to this is predicated on your patient mix. If you have a high volume of Medicare patients, like many ophthalmology and optometric practices, your cuts could still be 2 – 4% for 2007. If you are an internal medicine or family practice clinician with a small amount of Medicare patients, your cuts might be negligible.

Going forward, the answer to this question becomes more dire. For instance, the hold on the CF for 2007 was temporary. And, an underlying, and moderately complicated concept in the reimbursement mix is the Sustainable Growth Rate (SGR), which "…is intended to control the growth in aggregate Medicare expenditures for physicians' services."[1] In theory, the goal of SGR is not intended to withhold payments for physicians' services. Instead, the SGR has expense targets set via mathematical gymnastics; if those targets, those actual expenditures, are exceeded relative to *projected* expenditures, then the update is decreased. (The update for 2006, for instance, examined cumulative expenditures from April 1, 1996 through December 31, 2005.) If expenditures are *less* than projected, the update is increased for the coming year. The SGR takes into account, as one of its components, real (inflation adjusted) gross domestic product (GDP). It can be argued that incorporating GDP into this convoluted calculus does not account for the fact that the economic activity measured by real GDP does not take into account the actual cost of providing care to patients. (Admittedly, a discussion on the SGR could be another article entirely; please go to Web links below for a more detailed discussion.)

When all is said and done, the SGR is thought by many to be a fairly flawed method by which to contain costs and as such, needs to be addressed, amended, and possibly thrown out. The problem is that there has been little action on this, to date, leaving 2008 reimbursements in question.

## What can be done?

Since the Congress acted, the cuts for 2007 have not been as dramatic as they could've been. Nonetheless, each practice should, once the fee schedule comes out in the fall of each year:




- evaluate the impact of Medicare's increase or decrease relative to their practice by examining patient volumes (if you don't want to visit all of your codes, you might select your top 20 procedures [the old "80/20" rule might apply where 80% of your business is derived from 20% of your codes]),
- get involved with the process; get your management team (administrator) involved,
- contact national legislators (try to go through their local offices) and discuss with them your thoughts

on the cuts and what those mean to you, especially given the fact that the cuts are expected, given the current structure, for the next three years, and

- run as efficient a practice as you can scrutinizing how you spend your revenue.

## Summary

Is Medicare at the breaking point? Are physicians leaving the program in droves? Quite to the contrary, based on a recent Congressional Budget Office report which stated that "More than 90 percent of physicians and non physician professionals…participate in Part B…" The report goes on to state, ominously, that "….the situation may change if payment rates are significantly reduced…"

Unless, or until, Congress amends the current SGR formulation, practitioners and their management teams will continue the fall ritual of scrambling to evaluate the impact the next round of cuts will have on their practices. With no change to the SGR, it is suggested that Medicare fees may be reduced 4 – 5%/year for the next several years. Can your practice handle that? And even if Congress keeps reimbursements static, that could conceivably be construed as a cut as the costs associated with running a practice are not declining, year to year. Clinicians participating in the Medicare program would do well to stay plugged in, educate themselves, run efficient practices, and reach out to their legislators to voice concerns about reimbursement.

If you have questions, please contact me directly at jeffgorke@garetina.com.
Jeff Gorke, MBA
Administrator



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2. CBO Economic and Budget Issue Brief, September 6, 2006, p.2; http://www.cbo.gov/ftpdocs/75xx/doc7542/09-07-SGR-brief.pdf
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## STATINS AND AMD *— continued from page 1*

### AMD: A Possible Connection to Atherosclerosis?

There are several lines of evidence suggesting a possible connection between atherosclerosis and AMD. For example, AMD has been associated with markers of atherosclerosis, such as carotid plaques and elevated pulse pressure. AMD has also been linked to risk factors for cardiovascular disease, including smoking, hypertension, and elevated serum and dietary cholesterol. Histologic evidence suggests that cholesterol accumulation in Bruch's membrane may play a role in the pathogenesis of AMD. Furthermore, lipids involved in the pathogenesis of atherosclerosis, (such as apolipoprotein B and E) are also located within drusen, and clinical measures of atherosclerotic severity (e.g., carotid artery thickness and ankle-arm ankle-brachial index) suggest that atherosclerotic plaques are positively correlated with AMD. These findings have led to the hypothesis that reducing serum and ocular cholesterol with HMG CoA reductase imhibitors (statins) may slow, stabilize, or reverse the progression of AMD in a manner similar to their modulation of cardiovascular disease. Furthermore, since there is also evidence that inflammation may play a role in choroidal neovascularization (CNV), statins may also modulate the inflammatory mediators involved in this process. Histological specimens from AMD patients with CNV demonstrate macrophages and other chronic inflammatory cells. When activated, macrophages release cytokines, including VEGF, which may contribute to CNV development in AMD patients.

### What are Statins and What is the Evidence?

Statins are a class of drugs that lowers serum cholesterol by reducing hepatic cholesterol production. Specifically, statins block the enzyme in the liver that is responsible for making cholesterol. This enzyme is called hydroxy-methylglutaryl-coenzyme A reductase (HMG-CoA reductase, for short). Scientifically, statins are called HMG-CoA reductase inhibitors. Their use in cardiovascular disease has been well-studied. It has been postulated that statins may impact on AMD by reducing cholesterol and/or by reducing mediators of inflammation. There has been much interest in determining whether statin use lowers the incidence and progression macular degeneration. For example, statins might prevent the accumulation of basal linear deposits in Bruch's membrane, which occurs with higher concentrations of plasma cholesterol (Hall, et al., 2001). Also, the antioxidant properties of statins might protect the outer retina from oxidative damage. There have been several studies reporting on the relationship of AMD progression and the use of statins. However, these studies have been conflicting and have been criticized because of either weak associations, small study population sizes, or because they show no relation with dose, type of statin, or duration of statin use.

McCarty et al. (2001) provided preliminary evidence suggesting that cholesterol-lowering medications may be associated with a reduced risk of progression of age-related maculopathy; in addition, Hall et al. (2001) reported in a cross-sectional study that statins may be associated with a reduced risk of AMD. However, these population-based studies included few patients on cholesterol-lowering medications, therefore rendering the data imprecise. In addition, two large population-based cohort studies found no significant association between lipid-lowering medications and AMD; the first (vanLeeuwen et al., 2003), measured cumulative exposure to cholesterol-lowering medications and found no association with risk of age-related maculopathy, whereas the second (Klein et al., 2003) found no association between statin use and the incidence of early AMD (odds ratio 1.12), progression of AMD (odds ratio 1.22) or late AMD (odds ratio 0.41) over a 5 year period in the Beaver Dam Eye Study with 2780 participants. However, Wilson et al. (2004) demonstrated in a retrospective consecutive case series that therapy with statins or aspirin is associated with a decreased rate of CNV among AMD patients. Interestingly, these authors also found that elevated serum triglycerides and low HDL levels were correlated with the rate of CNV development.

In addition to their lipid-lowering effects, statins have anti-inflammatory properties. New research shows that statins reduce inflammation, which could be another mechanism by which statins beneficially affect atherosclerosis. This reduction of inflammation does not depend on statins' ability to reduce cholesterol. Further, these anti-inflammatory effects can be seen as early as two weeks after starting statins. Statins inhibit activation of transcription factors such as Rho and NF-κB, which mediate inflammation, reduce recruitment of and cytokine release from inflammatory cells, and reduce macrophage survival. Statins also have antioxidant properties and antioxidants have been shown to reduce risk of CNV in AMD patients (Age-related Eye Disease Study).

### Are There Differences Among Statins?

Statins differ in several ways. The most obvious difference is in their ability to reduce cholesterol. Currently, atorvastin (Lipitor®) is the most potent and fluvastatin (Lescol®) is the least potent. A new statin, rosuvastatin (Crestor®), and a combination ezetimibe/simvastatin (Vytorin®), may be more potent than atorvastatin. The statins also differ in how strongly they interact with other drugs. For example, pravastatin levels in the body are less likely to be elevated by other drugs because the enzymes in the liver that eliminate pravastatin (unlike the enzymes that eliminate other statins) are not blocked by most other drugs. Interestingly, pravastatin, simvastatin, and lovastatin are derived from natural sources and have similar chemical structures. The other statins are completely synthetic and have chemical structures that differ greatly from the natural statins. With respect to AMD, no study to date has actually stratified their data with regards to statin type and its effect on the late complications of the disease. Therefore, it is currently not known whether all statins would be equally efficacious in our patients with AMD.

### What are the Potential Side Effects of Statins?

All medications may be associated with potentially serious side effects. The most common side effects of statins are headache, nausea, vomiting, constipation, diarrhea, headache, rash, weakness, and muscle pain. In addition, liver function enzymes must be monitored periodically as the risk of persistent liver enzyme abnormalities while taking a statin is about 0.5-3%, occurring usually in the first 3 months of therapy. This adverse effect is more common at higher medication doses and is almost always reversible when the drug is stopped or reduced. Muscle abnormalities, ranging from muscle soreness (myalgias) to muscle inflammation (myositis) to muscle breakdown (rhabdomyolysis) have been described. In the case of myalgias and myositis, muscle enzymes may be elevated in the blood, and the condition is generally reversible upon discontinuation of the agent. The most severe and fortunately rare side effect is rhabdomyolysis, which can begin as muscle pain and can progress to loss of muscle cells, kidney failure, and death. It occurs more often when statins are used in combination with other drugs that themselves cause rhabdomyolysis or with drugs that prevent the elimination of statins and raise the levels of statins in the blood.

### What is the Verdict?

Without direct proven efficacy of statins in preventing complications associated with late AMD or reducing the overall relative risk of developing such complications, it is best *not* to recommend these drugs to our patients with AMD for the sole purpose of treating their AMD. The pleiotropic effects of statins, though well characterized for cardiovascular outcomes, have yet to be definitively linked to a reduction in AMD risk. Thus, only through a well-conducted, prospective, randomized, controlled clinical trial will accurate data be obtained. Unfortunately, such a trial may be difficult to complete due to the excess cardiovascular risk among the placebo group. *-RAS*

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