MIDNIGHT IN THE GARDEN OF GOOD AND EVIL -
RECENT DEVELOPMENTS IN THE QUI TAM ARENA

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I. ARE THERE REALLY A HUNDRED DRUG CASES OUT THERE?

Drug cases were once as rare as satellites in the 1950s ... and are now as numerous as
satellites in the twenty-first century, which means that they will occasionally collide with one
another, or simply fall out of orbit, raining debris across the landscape. Since the debris will be
legal and conceptual, it matters little if it falls on us or near us, as we shall all be effected by the
precedents established, and will all have to work our way through the confusion sown. The
most remarkable thing about the sheer numerosity of cases is what it will drive B and that is a
search for simplifying principles. One of the most powerful of those principles is a Abest price@
damage analysis.

II. A BEST PRICE PRIMER

Government payment for drugs comes in several flavors. Outside of the Medicaid and
Medicare programs, the government procurement goes through the Federal Supply Schedule
(FSS), which has its own ways of calculating and negotiating prices. Because here the federal
government has been able to fully use its weight in the marketplace, FSS prices are much lower
than prices charged to Medicaid and Medicare programs. FSS rules, set forth at 38 U.S.C.
'8126, require reporting of all prices calculate payments based on the non-Federal Average
Manufacturer=s Price (nonFAMP or NFAMP). As with the Medicaid rebate statute, subsect
8126(h)(5)(B) excludes from best price calculations any prices found by federal agency
involved to be >nominal in amount=.

Medicaid rebates work similarly, with each state given a 15.1% rebate off of AMP or the
best price available B whichever is less. Again, nominal prices (10% or less of AMP) need not
be reported.

III. WHY ARE BEST PRICE CASES ATTRACTIVE?

A. Industry Predilection

Evading the >best price= reporting requirements appears to some to be one of the more popular sports among PhRMA. One industry observer B and a defense lawyer at that B has termed use of nominal pricing >fairly common=. If, as Simon & Garfunkle put it, there are Fifty Ways to Leave Your Lover, there must be at least as many ways to lower your price without reporting it to Medicaid. Thus, hospitals, health systems, and managed care networks all get showered with stock bottles, grants, spurious >value added= projects, or old-fashioned >lick and stick= fraud, via the questionable creation of new NDCs for old drugs in standard dosages.

B. Government and Whistleblower Predilection

From an enforcement perspective the best case is one where the defendant has done just one thing wrong B but has done it several million times. The government need only prove it wrong once B and having established that, you get out your calculator. Thus, the attraction for developing a >best price= damages theory around a kickback case becomes a powerful one. As a simplifying principle, it can serve to cut through many other knottier calculations.
IV. WHAT THIS MEANS IN TERMS OF INDUSTRY TROUBLE SPOTS

“If we wait for Legal to clear this we won’t have any market share left.” (Beleaguered Sales Executive.)

When a company’s competitor is catching fire and national accounts hang in the balance, the tension between sales and everyone else can become overwhelming. As can the pressure to cut a corner. Or two. Or three. So Sales looks desperately for ways to offer deep-dish discounts without effecting best price calculations. And the guardians of compliance look for ways to stop them.

Although compliance officers are often accused of Monday-morning quarter backing, the only alternative is for an effective compliance effort is real-time line backing. Identifying drugs that are under competitive pressure or threatened lockouts may be the only way to intervene before the damage is done. Real-time price calculations are another, so that sales managers will know what the line is in terms of real reductions, whatever they are called. It is undeniably hard, and there will certainly be resistance, but it is possible to be aggressive without being suicidal. We count on military commanders to know the difference every day, and for what your sales execs are being paid, your companies are entitled to expect this of their tactical leadership.
V. **A CLOSE LOOK AT NOMINAL PRICE ... THE NATURAL HISTORY OF AN UNNATURAL PRACTICE.**

The best price requirements of the Medicaid Rebate program were established by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA >90) and then modified section of OBRA >93, and the section 601(b) of the Veterans= Health Care Act of 1992. HCFA, the CMS predecessor agency, made it clear that a best price@ will include cash discounts, free goods, and rebates (except for those specifically permitted by the Act.) As Congress directed, nominal prices are excepted from this reporting requirement. Hence the sales exec=s cri de coeur ABut its only nominal!@.

But what *did* Congress direct? The only language in the Congressional report accompanying the bill gave, as an example of nominal pricing, practically giving drugs away to charitable undertakings, such as Planned Parenthood! Moreover, both Sen. Finance Committee Chairman Charles Grassley and Rep. Henry Waxman, who at the time this bill passed chaired the House subcommittee responsible for this legislation, are adamant that:

AWhen the rebate requirement was enacted, Congress created an exception to determining the Best Price for drug sales involving prices that were merely nominal in amount (Nominal Price Exception/NPE). Congress was trying to address a particular concern in establishing the Nominal Price Exception; namely, to ensure that manufacturers did not have an incentive to terminate steep discounting practices designed with charitable intent to promote access to medication for low-income or other populations for which access might be limited.@

(April 29, 2004 letter from Sen. Grassley to major pharmaceutical manufacturers.)
There is equally strong evidence of administrative agency intent. An October 7, 1996 letter from the VA warned that:

- The nominal" pricing exclusion in the Act was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price. VA views "nominal pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose. Accordingly, low-price sales that do not fit this description may not be excluded from non-FAMP as sales made at a nominal price.

(ADear Manufacturer letter, October 7, 1996.)

And CMS, although less blunt, has also signaled that this will not be permitted. In the 1995 commentary which accompanied the rebate regulations, made it clear that the purpose of the nominal price exception was to ensure sales that Congress intended to be excluded (those to charitable organizations) were excluded, and that commercial sales are properly included in best price reporting. (60 Fed. Reg., 48478, September 19, 1995.)

Finally, in its Compliance Program Guidance for Pharmaceutical Manufacturers, OIG commented that:

- Pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. In many cases, the research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients. However, as with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.

VI. WHAT TO LOOK OUT FOR?

Be especially wary of >discount plus@ cases, where the discount is only a part, albeit an integral part, of the allegations. Discounts intended to move market share, push volume or get preferred status on a formulary will all be subjected to increasing scrutiny.

Be suspicious of alternative@ proposals, were your sales people are saying, AYou don=t like stock bottles? Well, how about a nice grant@? These will increasingly be seen for what they are B and are more likely than ever to be exposed to the light of day.