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**IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE**

STATE OF ALASKA,)	
)	
Plaintiff,)	Case No.: 3AN-06-12026 CI
vs.)	
)	ALASKA'S OPPOSITION TO GENERIC
ALPHARMA BRANDED PRODUCTS)	DEFENDANTS' MOTION TO DISMISS
DIVISION INC., et al.)	
)	
Defendants.)	

Certain manufacturers of “generic” drugs (hereafter called the Generic defendants) have filed a separate motion to dismiss some unspecified number of “multi-source” drugs from this lawsuit. They argue that the State of Alaska paid providers for these drugs, not under a formula depending on “average wholesale price” (AWP), but rather at the “Federal Upper Limit” (FUL), which is a specific price established for these drugs by the federal government. Hence, the Generic defendants argue, even if they conveyed false and inflated AWP information to medical compendia as alleged in the Amended Complaint (hereinafter “Complaint”), those false and inflated AWPs played no role in the State’s payments to providers for these multi-source drugs.

As this brief will show, the Generic defendants’ argument has no merit. Section I will discuss the regulatory provision they base their argument on – the Federal Upper Limit or “FUL” – in the context of other regulations governing how much the states are permitted to pay for drugs, particularly multi-source drugs. Section II will show that the Complaint alleges that, but for the defendants’ reporting of phony and inflated AWPs about multi-source drugs, the State would have paid providers for those drugs at less than the FUL prices it actually paid. Section III will conclude by showing that there is no merit to the defendants’ argument that the State fails to allege, as to multi-source generic drugs, “reliance” on defendants’ false reporting of AWPs.

I. The Federal Upper Limit is Only a Ceiling on What Alaska May Reimburse for a Drug, Not a Mandated Payment Amount.

The keystone of the Medicaid program's prescription drug benefit is the concept that states must aim to reimburse "providers" – the pharmacists and doctors who dispense prescription drugs to Medicaid recipients – at the providers' cost and nothing more. Federal regulations mandate that Alaska pay no more than the "estimated acquisition cost" (EAC) of the drugs plus a dispensing fee. 42 CFR § 447.331. The estimated acquisition cost is the price at which drugs are generally and currently available. 42 CFR § 447.301 ("Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.")

This rule applies with a special twist to multi-source generic drugs. Generic drugs are identical copies of brand name, patented drugs. Generic drugs generally enter the market when a patent expires on a brand name drug, freeing up other manufacturers to copy the ingredients of the brand name drug. The entry of generic drugs into the marketplace almost always leads to a dramatic drop in the actual sale price of the drug, but no drop in the reported average wholesale price. In turn, this often leads to a very large spread between the providers' real acquisition cost and the published average wholesale price. For example, after the drug Bupirone came off patent in 2001, it had a spread between the published AWP and the real average wholesale price of 34%. Four years later, because of the drop in the sale price, the difference between the false, published AWP and the true

average wholesale price was an astonishing 1,118%. *See* Amended Complaint (“AC”), Ex. C (under defendant Mylan).

Multi-source drugs are simply generic drugs which have multiple sources. “Multiple source drug’ means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.” 42 CFR § 447.301.

When pharmacists receive a prescription for a generic, multi-source drug, they can choose from a number of different manufacturers, some of whom sell the drug at a higher price than others. The State has no control over which source the pharmacists choose. One reason for allowing pharmacists this latitude is that they may not be able to purchase from the lowest-cost source.

To insure, however, that the pharmacist does not, for whatever reason, choose a generic that is being sold for a price significantly higher than other available generic versions, federal regulations put a ceiling on how much will be reimbursed for a multi-source drug whose price exceeds the lowest cost source. That ceiling is the Federal Upper Limit or “FUL.” The federal government has established FULs for multi-source drugs that have at least three suppliers.

The net effect of the regulations is this. When filling prescriptions that can be filled by generic drugs with more than one source, pharmacists need not choose the lowest cost multi-source generic. If they choose a higher cost generic version, they will generally be

reimbursed at cost -- but only so long as the cost does not exceed the FUL for that drug, which is set at 150% of the cost of the *lowest-cost* generic. As a practical matter, this puts a ceiling on the cost of multi-source drugs. 42 CFR § 447.332.

The crucial fact for purposes of the present motion is that, in paying providers who dispense multi-source generics to Medicaid patients, states are *not required to pay the FUL*. Since states are required by regulation to aim to pay providers no more than cost, they would not *want* to pay FUL if the provider's cost to obtain the drug is significantly lower than the FUL. Thus, to comply with the basic mandate of paying no more than estimated acquisition cost, the State would want to pay FUL only if FUL is no more than the amount billed *and* no more than the State's estimated acquisition cost of the provider. 7 ACC § 43.591(c)-(d) (2006). As the Generic defendants' own exhibit states: "In-state pharmacies are reimbursed for most drugs by the following formula: at lowest of the billed amount, acquisition cost (EAC) or FUL" Exhibit 1 to the Generic Defendants' Motion To Dismiss, p. 22.

In short, the FUL operates only as an upper bound on what Alaska is willing to reimburse a pharmacy for a multi-source drug.

II. The Complaint Alleges That Defendants' Scheme Artificially Inflates The Price The State Paid To Providers Of Multi-Source Drugs

The Complaint describes a scheme by defendants to inflate artificially the prices of all their drugs, multi-source drugs included. Although the Medicaid program for paying for prescription drugs is vast and complicated, the scheme the defendants used to disrupt it is simple enough. In essence, the Complaint alleges that defendants corrupted the pricing

databases relied upon by the State in setting its payment rates by supplying these databases with prices for their drugs which they knew were false and inflated. This interfered with the State's ability to estimate accurately the price at which providers were purchasing their drugs, causing the State to overpay by a huge amount for the drugs prescribed for its citizens. The scheme is summarized in more detail in Alaska's Opposition To Defendants' Joint Motion to Dismiss.

In paragraphs 34-40, the State alleges that it depends on up-to-date electronic pricing data to estimate providers' acquisition cost of defendants' drugs:

As a practical matter, Alaska, like most other states, is dependent on the medical compendia for the maintenance of its Medicaid claims processing system. When a pharmacy fills a prescription and dispenses a drug to a Medicaid patient, information regarding that prescription is communicated electronically to Alaska through the Point-of-Sales claim processing system. On a weekly basis, First DataBank electronically sends its updated AWP's for the thousands of NDC-numbered drugs listed in its database to First Health to update Alaska's Medicaid file. These prices become the basis for Alaska's reimbursements to providers. There is no other electronic source of this information. Accordingly Alaska is functionally dependent on the accuracy of the data defendants supply to First DataBank in meeting its obligation to pay providers not more than their actual acquisition cost of defendants' drugs.

Paragraphs 41 through 47 describe how defendants corrupted the prices published in the pricing compendia used by Alaska, and allege that: "All of the defendants have inflated their . . . reported AWP's to levels far beyond any real average wholesale price for their drugs." AC ¶43.

The Complaint then goes on to allege that this scheme has impacted multi-source drugs in two different ways. First, the true prices at which defendants' drugs were sold were in all cases well below the published FUL prices which the State actually paid. Since

the State was required to pay no more than the acquisition cost of the drugs—the true price of defendants’ drugs—had defendants provided truthful information about their drugs’ AWP, then the compendia would have published lower AWP for those drugs, and the State, rather than use FULs to estimate providers’ acquisition costs for those drugs, would have used those more accurate AWP, and thereby would have paid less than the FULs.

Second, the Complaint alleges that the FUL is based on the phony, inflated prices published by defendants. It doesn’t matter which multi-source drug is used as the baseline to calculate the 150% ceiling because, as the Complaint alleges, all drugs of all defendants were and are inflated. Thus, every FUL is based on an inflated price.

Both these theories are set forth succinctly in paragraph 71 of the Complaint, which states:

For a minority of the drugs purchased by Alaska, the state sets its reimbursement rate at either the federal upper limit (“FUL”) or at a rate established by the state maximum allowable costs (“MAC”) program. For multi-source drugs that have at least three suppliers, the Center for Medicaid Services (“CMS”) generally establishes FULs, defined as 150% of the least costly therapeutic equivalent (using all national compendia) that can be purchased by pharmacies in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. 42 C.F.R. § 447.332. As a practical matter, CMS has relied on the defendants’ inflated prices to set most of its FULs. The states also may set reimbursement rates for these drugs at rates lower than the FUL pursuant to the state MAC program and Alaska has done so in a number of instances. Had defendants reported truthful prices, the FULs and state MACs would have been lower. In addition, had defendants reported truthful prices, the State would not have paid based on FULs or MACs, but rather based on truthful AWP.

In sum, the Complaint specifically alleges that Alaska overpaid for its multi-source drugs as a direct result of defendants' campaign of publishing false and inflated wholesale prices.

III. Defendants' "Reliance" Argument Is Meritless.

The Generic defendants argue that, even if they reported false and inflated AWP data about multi-source generic drugs, the State fails to allege that the State relied on this data, and therefore cannot recover as to those drugs. This is wrong.

First, as discussed in detail at p. 13 of the State's Memorandum In Opposition To Defendants' Joint Motion To Dismiss, the Unfair Trade Practices Act contains no "reliance" requirement of any kind.

Second, the State *does* allege that the State relied on the Generic defendants' false and inflated AWPs. It alleges that it relied on the pricing publications and the prices they reported to tell it when the estimated acquisition cost of defendants' drugs was less than the FUL. As we now know, the true acquisition cost of defendants' drugs was lower than the FUL in every case. Thus, as explained above, had defendants reported accurate AWP information, the State would have been able to use this information to pay providers at the true acquisition cost of the drugs, which was always lower than the FUL.

Moreover, as the Complaint alleges, the federal government used defendants' published, inflated prices in setting its FUL, and the State relied on the federal government's FUL list as a means of estimating what providers' real acquisition costs were. This is no figment of the State's imagination. The FUL list, which defendants cite, makes

its reliance on the corrupted pricing compendia clear. Transmittal No. 37 states: “The (FUL) listing is based on data current as of April 2001 from the First Data Bank (Blue Book), Medi-Span, and the Red Book.” <http://www.cms.hhs.gov/FederalUpperLimits>, reprinted in Exhibit 1 attached hereto.

IV. Defendants’ “Particularity” Arguments Have No Merit

In its Opposition to Defendants’ Joint Motion to Dismiss, the State has answered the defendants’ arguments about the “particularity” of the Complaint. Here, the State will limit itself to observing that the examples of lack of “particularity” offered by the Generic defendants only serve to emphasize how meritless the argument is.

For example, the Generic defendants argue that they are unable to understand and respond to the Complaint because the State has failed to allege, as to each drug it lists, whether the State reimburses that drug on the basis of AWP or the FUL. Defendants’ Generic Memorandum, 8. If there is one fact that each Generic defendant knows, it is the identities of the drugs that Alaska reimburses on the basis of FUL versus AWP. For example, the Generic defendants tell the Court all about Sandoz’s drugs in this respect. *Id.*, 10-11. Whatever the purposes of the “particularity” requirement of Rule 9(b), those purposes do not include the purpose of unnecessarily bloating the size of complaints by making plaintiffs plead facts that the defendants concede they already know.

In short, the Generic defendants’ argument for carving out, on this motion to dismiss, some unspecified number of multi-source drugs from the scope of the State’s case has no merit. The State alleges, and will prove, that if the Generic defendants had supplied honest

data about their drugs' AWP's, the State would have paid providers at rates lower than the FULs at which they actually paid. The Complaint pleads this conduct with more than enough specificity to allow the Generic defendants to admit or deny whether they engaged in this scheme or not.

* * * * *

The separate motion to dismiss of the Generic defendants should be denied.

FOSLER LAW GROUP, INC.
Attorneys for Plaintiff

DATED: _____

By: /s/ James E. Fosler
James E. Fosler
Alaska Bar No.: 9711055

CERTIFICATE OF SERVICE

Pursuant to Case Management Order No. 1, entered by the Court in this case on December 14, 2006, the undersigned certifies that a copy of the foregoing document was served through the LexisNexis File and Serve ("LNFS") system on February 9, 2007.

 /s/ James E. Fosler
James E. Fosler

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