

September 30, 2002

Donald S. Clark Office of the Secretary Federal Trade Commission 600 Pennsylvania Ave., N.W. Washington, D.C. 20580

Re: Comments Regarding Competition Law and Policy & Health Care

Dear Mr. Clark:

At the September 10, 2002, FTC Workshop on Health Care and Competition Law and Policy, a representative of the Medical Device Manufacturers Association (MDMA) made a presentation that began with the question "GPOs – Is There A Problem?" Novation, the supply chain management company for VHA Inc. and University HealthSystem Consortium (UHC), two alliances comprised of community-owned not-for-profit hospitals and academic health systems throughout the United States, is a leader among GPOs. Our focus is to help the hospital members of VHA and UHC realize efficiencies and cost savings in their purchasing functions, and our purchasing programs have saved VHA and UHC member hospitals approximately \$2.1 billion since our inception in 1998.

We at Novation believe that the MDMA painted a seriously flawed picture of GPOs in general, and offered descriptions of contracts and purchasing programs that are factually inaccurate with regard to Novation in particular. We want to take this opportunity to correct the record, and we do so by addressing the statements contained on the slides presented by the MDMA (a copy of the slides is attached for reference). Notably, however, while we disagree with much of what the MDMA has said, with the MDMA's main accusation – that we help hold down prices through a competitive bidding process – we completely agree.

Slide 2: GPOs – Is There A Problem?

Indeed, we believe there is a problem – for manufacturers trying to charge high prices for their products. MDMA members would much prefer if Novation and other GPOs did not exist at all, because that would eliminate the ability of hospitals to save money through group purchasing. The result would be higher profits for MDMA members, but at the expense – literally – of hospitals, patients, and taxpayers.

Some tension between sellers (in this case, MDMA members) and buyers (represented by GPOs as their purchasing agents) is normal and healthy in a free marketplace. But the MDMA's complaints to the FTC amount mostly to sour grapes – the belief by some companies that they should have received a contract when they didn't. Any competitive bidding process results in winners and losers. The GPO system is doing exactly what Congress intended it to do: rewarding manufacturers that can supply the best combination of price, quality and service. That is the major reason why 96% of U.S. hospitals use GPOs.

The MDMA tries to portray GPOs as stand-alone companies that interfere with the relationship between hospitals and suppliers. But, especially in the case of Novation, *everything we do is for the benefit of our members*, through the cooperative structure of our parent organizations, VHA and UHC. And all participation in every one of our programs is entirely voluntary. If we were not serving the best interests of our members, we would cease to exist. (In addition, studies show that if GPOs did not exist, the average hospital would pay \$353,000 to replicate those purchasing functions.)

Slide 3: Exclusionary Agreements

Sole-source agreements: This statement mixes several concepts and is typical of the lack of clarity with which the MDMA describes GPO contracts. "Sole source" simply means that Novation has one contract for a given product category. But no Novation contract, whether sole source or multi-source, requires member hospitals to buy from the contract supplier. A member is always free to ignore the contract and purchase from an alternative supplier. All participation in Novation's agreements is voluntary. The mere fact that Novation has a sole source contract for a product does not, by itself, mean that there is any "compliance requirement." We also note that Novation offers dual source or multi-source agreements for many products, especially those with high clinical preference. In fact, more than 60% of Novation agreements are dual- or multi-source agreements. Moreover, to the extent the MDMA was referring to Novation when it stated that many GPO contracts last 7 years, that is inaccurate. Most of our contracts are three years, with options for additional one-year extens ions, but our contracts typically can be canceled on short notice by both Novation and the supplier.

In referring to "compliance requirements," the MDMA seems to be addressing the *content* of certain Novation contracts as opposed to their sole source nature. Some of Novation's contracts provide that a member can receive a lower price if it chooses to purchase a percentage of its requirements (sometimes up to 95%, but sometimes less) from the contract supplier. But there is never any *requirement* that a hospital reach the specified level of commitment; participation in a committed program is always entirely voluntary. Members can choose to make the commitment and get a lower price, or they can choose not to make the commitment. On many of Novation's contracts, a sizeable number of hospitals elect not to make the commitment. This fact indicates that the hospitals are not coerced or pressured into purchasing at a committed level. Moreover, Novation has many contracts, both sole source and multi-source, that do *not* offer lower prices for commitment. For example, in Novation's contract with Becton Dickinson for blood collection devices, there is only one price for each product. Members cannot get a lower price by committing to purchase any percentage of their requirements of blood collection products from Becton Dickinson.

The MDMA also makes reference to "exclusive dealing consequences." It is well known that the consequences of exclusive dealing can only be determined by analyzing the foreclosure effect of the arrangement in a defined product and geographic market. The mere fact that a GPO contract may encourage buyers to commit to purchase a product from a single supplier does not mean that competition has been or is likely to be harmed; quite the contrary, exclusive dealing arrangements have long been recognized as procompetitive and for that reason are routinely sustained by the courts. Without any analysis of the product or geographic markets at issue, and

without any analysis of the level of foreclosure the results from a particular contractual arrangement, it is meaningless to talk of "exclusive dealing consequences."

Bundling: Again, it is important to be specific when talking about contracts or bundling. Novation has a program called Opportunity. The concept of the Opportunity program is that hospitals commit to buying a specified percentage of their requirements (sometimes 95%, sometimes less) of a group of different products contained on several different contracts. (Each of these contracts is independently awarded, and only after the contract award is a contract considered for inclusion in the Opportunity program.) In exchange for their commitment, members receive the lowest prices available under the contracts, and they also receive additional rebates. Those rebates are paid directly by the manufacturers to the hospitals, not by the GPOs as MDMA suggests. As a result of participating in the Opportunity program, hospitals can achieve significant reductions in their per-unit acquisition cost of a variety of medical supplies.

Participation in the Opportunity program is entirely voluntary. Just over half of Novation's hospitals participate; the others have decided that, for whatever reason, they do not want to make the commitment to purchase from the suppliers whose contracts are in the Opportunity program. The program enables participating members to receive deep discounts on a range of products. Of course, when hospitals sign up for Opportunity, they make a decision to "exclude" other manufacturers in exchange for lower prices. But like any decision by a purchaser to select one supplier over another, "exclusion" can be harmful to competition only if it forecloses a substantial share of the relevant market to competitors. Given that only half of Novation's members participate in Opportunity, it is hard to imagine that this form of exclusion could be anticompetitive, and MDMA certainly has not provided any hard evidence to support its allegations.

Vendor fees: Vendor fees are common for purchasing cooperatives in many industry segments. Novation's fees are fully disclosed to members, which also receive a large share of fees in the form of cooperative payments.

The payment of fees by vendors is the mechanism by which GPOs fund their group purchasing activities. In the case of Novation, vendor fees also go to support its parent alliances, VHA and UHC, which use the fees to offer a wide variety of programs designed to benefit their member hospitals. These include everything from clinical improvement programs to benchmarking to assistance with purchasing capital equipment. The MDMA has presented no facts to support its contention that vendor fees have diverted Novation from its core mission of serving its member hospitals.

Price control: We do not know what the MDMA is referring to, as it has not offered any evidence that Novation engaged in this practice. But the notion that Novation would condition a supplier's participation in a Novation contract on offering a higher price makes no sense at all. Novation competes with other GPOs for hospital members, and it would lose those members if it required contract suppliers to raise their prices.

Slide 4: Masimo: Our GPO Experience

This is a distortion of Novation's contract. First, nothing in the Novation-Nellcor agreement, or in Novation's participation agreements with its members, provides that members "can only buy" Nellcor pulse oximeters. If a member decides to purchase this product from Masimo or another vendor, it is perfectly free to do so. Second, the Novation contract with Tyco/Nellcor contains four price tiers. Three of those tiers require no purchasing commitment at all, but instead are based on dollar volume of purchases. (We do not understand the MDMA to be complaining about volume discounts, which of course are common and almost never offend the antitrust laws.) The fourth tier provides a deeper discount to hospitals that elect to commit to purchase 95% of their needs from Tyco/Nellcor. The MDMA claims that hospitals are "penalized" for not reaching the 90-95% "compliance levels," but it is not a "penalty" to offer a buyer a lower price for commitment and to withdraw that lower price if the hospital does not reach the commitment level. Third, we do not know precisely what the MDMA means by "exponential" price discounts, but this word – like many others used by the MDMA and critics of GPOs – seems calculated mainly to shock the listener. In fact, the committed tier of the Novation-Nellcor contract does not offer prices that are "exponentially" lower than the other tiers.

With regard to bundling, the MDMA offers no empirical support for its claim that purchasing from Masimo would cost hospitals \$500,000 to \$1 million. Nellcor pulse oximeters are part of Novation's Opportunity program, and, as mentioned earlier, hospitals can earn additional rebates by committing to buy certain percentages (up to 95%) of their needs of several different products from contract suppliers. As noted, only about half of Novation hospitals participate in Opportunity, so to the extent this statement is intended to apply to all of Novation, it is false.

Slide 5: Success in Free Markets

Neither the MDMA nor Masimo has explained this chart in any meaningful way. First, we do not know what Masimo means by "lost deals." That could refer either to lost sales at individual hospitals, or lost competitions for GPO contracts. If the former, we find it utterly implausible that Masimo never lost a single sale at an Amerinet hospital or an "Independent Hospital," while at the same time converting 60% of all members of those groups (Amerinet alone contains over 1,000 hospitals) to its product. No medical device supplier, indeed no supplier of any product, is that successful. Second, Masimo provides no context for the statistics. We do not know the total number of hospital members of any of the five listed GPOs to which Masimo attempted to sell, so there is no way to evaluate the acceptance rate of Masimo's product.

Slide 6: Masimo Price

This slide is fake, misleading, and a classic case of comparing apples and oranges. Specifically:

- A review of Masimo's cost analysis indicates that Masimo compared its sensor to Nellcor's most expensive sensor. Those sensors are *not* the most typical matches used in a cross-reference comparison.
- In addition, Masimo has claimed that its sensors are less expensive because they last as long as 14 days, thus requiring fewer replacement sensors. However, this does not reduce costs in most cases because the average length of stay in member hospitals for the typical ICU patient and on general medical-surgical floors is much shorter than 14 days.
- When reviewing the cost analysis during his testimony before the Senate subcommittee, Masimo's CEO, Joe Kiani, neglected to inform the panel that Masimo submitted a joint bid to Novation with Datex-Ohmeda. Thus, all products from both companies were analyzed as one proposal; Masimo pricing was not analyzed separately.
- In addition, Nellcor was the only manufacturer to offer the cost-reduction service of recycling disposable pulse oximetry sensors. This program reduces hospital expenditures on disposable sensors by 20 to 40 percent.

Again, we must emphasize that this contract – like all Novation contracts – was reached after an open, transparent public bidding process. If Masimo had made the best bid, following input from our reviewing council composed of representatives of member hospitals, it would have received a contract.

Slide 7: Bundling Schemes – Novation's Opportunity Spectrum Program

In the third bullet point, the MDMA misrepresents the effect of failing to remain compliant with Opportunity and provides no empirical support for its numbers. First, a hospital that becomes non-compliant loses the product discounts it would otherwise enjoy if it had remained in the Opportunity program. The hospital simply goes back to paying the same prices that non-Opportunity hospitals pay for products included in the Opportunity program. The non-compliant hospital does not "lose" money, whether \$500,000 per year or some other amount; it simply does not get a discount that would otherwise be available if it had chosen to stay in the Opportunity program. Second, while the terms of the Opportunity program provide that a hospital that becomes non-compliant must return the rebates it has earned from the beginning of the program period, that requirement has been interpreted very liberally by Novation and would only be enforced for long-term non-compliance.

Slide 8: Gibbons

First, the claims that Gibbons Surgical can produce "40 to 70 percent savings" over a competitor's product are unsupported and difficult to believe. Second, it should be noted that Gibbons actually *does* have a contract with Novation, so its main complaint seems to be that it would like more business – something that is probably true of most manufacturers in any industry. In addition, we note that on multiple occasions Novation has provided Gibbons with a targeted list of hospitals that do not participate in the Opportunity program and that might be likely customers.

Slide 9: RTI Impact of Anticompetitive Conduct

RTI has brought an antitrust lawsuit against Novation and Premier (with which it has had contracts since 1999). These are general allegations that RTI has made in the lawsuit but that have not been proven. Nonetheless, it is highly disingenuous for RTI to claim, for example, that market entry has been restrained in the market in which it competes (needles and syringes), where (i) RTI has secured GPO contracts with virtually every large GPO except Novation, (ii) RTI has an agreement with Abbott Labs under which Abbott's huge sales force sells RTI products in acute care hospitals, (iii) RTI has steadily increased sales in the five years it has been a competitor, (iv) new and improved needle and syringe products continually have come on the market, (v) new competitors, such as SIMS Portex have entered and thrived, and (vi) prices have steadily decreased. RTI's allegations seem calculated mainly to force GPOs to give RTI a contract.

Slide 10: Retractable's Experience with GPOs

To begin with, the suggestion that RTI's experience with GPOs consists of one unsuccessful interaction with Baptist Health System of San Antonio (a Novation member) is highly misleading. As indicated above, RTI has contracts with most of the leading GPOs, including Premier, Amerinet, HSCA, Insource, and MHA/Medecon. That is public knowledge, posted on RTI's website at www.vanishpoint.com/purchaser/7.html. RTI also has a contract with the Veterans' Administration and has a distribution agreement with Abbott. In fact, three years ago RTI boasted in press releases that it had secured contracts with four of the five largest GPOs in the country, giving it access to thousands of hospital customers – hardly a bad experience.

RTI has repeatedly alluded to this statement and it is alleged as a fact in its complaint against Novation. Novation believes that the assertion is not true. In any event, the statements suggests that Baptist – which was a member of the Opportunity program – was concerned that it would lose rebates if it bought RTI's syringes instead of the Becton Dickinson syringes that were on contract and included in the Opportunity program. But the mere fact that Baptist or any Novation hospital in the Opportunity program chose to deal exclusively with a supplier other than RTI in order to get deep discounts and rebates is not anticompetitive. The total volume of syringe purchases made by hospitals that participate in the Opportunity program, compared to the total volume syringe purchases in the United States, is far too small to foreclose competition in any meaningful way. Any decision Baptist may have made to forego purchasing RTI's

syringe is symptomatic of nothing but competition, and RTI's suggestion that this alleged statement shows a competitive problem is unfounded.

Slide 14

Most of these are allegations for which there simply is no empirical support – only the assertions of self-interested members of the MDMA. With regard to the GAO study, it is bears repeating that a GAO representative publicly stated at the workshop that the study was preliminary, limited in scope, and that a more comprehensive analysis was required and in progress. Given the extremely limited scope of the GAO's analysis, it is unfair to suggest or to conclude that GPOs do not save their members money. To the contrary, the overwhelming evidence on the public record shows that GPOs save hospitals tens of millions of dollars annually.

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We hope that this information is helpful in clarifying and correcting some of the issues raised by the MDMA, and we welcome additional opportunities to publicize the value and benefits we bring to community-owned and academic medical centers around the country.

Sincerely,

Jody Hatcher

Vice President, Novation