nova
biomedical

November 7, 2003

Mr. Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Comments Regarding Hearings on Health Care Competition and Policy

Dear Mr. Clark:

Nova Biomedical ("Nova") hereby submits the following comments relating to the September 26, 2003 Federal Trade Commission and Department of Justice Health Care and Competition Law and Policy hearing on Group Purchasing Organizations ("GPOs"). Nova appreciates this opportunity to comment on the anti-competitive contracting practices of GPOs that continue to cause participating hospitals (and the ultimate consumer) to pay higher prices for health care products of lesser quality.

Nova Biomedical is a manufacturer of sophisticated blood gas/critical care analyzers that are used by hospitals in support of the hospital's most critically ill patients. Blood gas analyzers are typically used in ICU, Surgery and ED to provide vital emergency (stat) blood tests on critically ill patients. The blood tests are often pivotal in making life and death decisions. Because of the sophisticated nature of the analyzers, differences in their test menus and other characteristics, and the important role they play in supporting critically ill patients, the purchase of these analyzers typically involves multiple hospital departments and personnel, including medical staff, clinical lab and administration.

Nova's blood gas analyzers are the newest and most modern technology in the industry. We offer more blood gas analyzer models, more blood gas analyzer test menus and more price choices than any other blood gas company. Nova has the most competitive pricing and the most pricing options of all the blood gas vendors.

Nova's market share in 2002 in the international market was 23% -- as high or higher than all other blood gas vendors – despite the fact that it is the only American vendor and all the other manufacturers are foreign-owned. On the "open" (non-GPO) U.S. market, Nova estimates that its market share is 24%, which demonstrates its strong sales when hospitals are not restricted by GPO practices. Notwithstanding this demonstrable market success, Nova to date has been unable to obtain a contract from Premier, Inc. ("Premier"), one of the nation's two largest GPOs, despite substantial marketing efforts.

Nova Biomedical, 200 Prospect Street, Waltham, MA 02454-9141 Tel: 781-894-0800, 800-458-5813, Fax: 781-894-5915
www.novabiomedical.com

## I. Despite Promises To Reform Their Own Conduct, GPOs Continue To Engage In Anti-competitive Contracting Practices Which Have Prevented Hospitals From Obtaining The Best Technology At The Best Prices

### A. GPO Contracting Decisions Are Not Based On Merit.

Given the extreme importance of blood gas tests to the survival of critically ill patients, blood gas analyzers are almost never selected by individual hospitals without first obtaining product demonstrations and technical evaluations in their own settings. Input from medical staff, who rely heavily on the blood gas analyzers in treating their critically ill patients, is of major importance.

Nova believes that GPOs often lack the technical and medical knowledge and expertise necessary to capably assess the merits of sophisticated capital equipment products for which they contract. Although at times they will seek some medical input, it is apparent that the purchasing decisions in fact are driven by others.

For example, in August, 2003 Premier made a blood gas analyzer decision on behalf of more than 1500 hospitals. As far as is known to Nova, that decision was made without having performed an evaluation of the instruments to benchmark analyzer performance and without involving input from medical staff on the need for certain test menus, processing speed, automated instrument self-testing, patient data trending or other medical preferences. In fact, Premier had no contact with Nova; provided Nova no opportunity to demonstrate it's newest analyzers; offered no public criteria for product selection; and, gave no explanation as to why it chose the selected suppliers.

It is extremely unlikely that any member of Premier's Laboratory Purchasing Committee had seen a demonstration of our new analyzers which offer three additional new tests not available on the contracted products. Premier could not have been familiar with their capabilities in any meaningful way before rejecting Nova for a new three year contract this past summer. Premier apparently chose not to evaluate the medical importance of these new tests in order to determine how they might improve patient care.

Despite promises in Premier's new "Code of Conduct," adopted in the wake of the Senate Judiciary hearings, to make its contract selection process more transparent, the most recent contract award process for blood gas analyzers demonstrates once more that Premier's practices remain secretive and uninformed. Nova now offers ionized magnesium, BUN and creatinine tests, which are not provided by other equipment manufacturers. These important new diagnostic tests are now available because of rapid technological progress over the last few years. These test results are all required to effectively treat critically ill patients because they can identify patients at risk for various types of emergency therapy and evaluate patients with cardiovascular abnormalities. A separate technology panel appointed by Premier to review products that qualify for a Technology Breakthrough Award determined in January of this year – prior to the August decision -- that Nova's newest blood gas analyzer was indeed a "breakthrough" – which requires a finding that the new product "offer[s] a significant advantage in terms of safety, improved clinical outcomes, or operational efficiencies." Although Premier's panel determined that Nova's product was a breakthrough, its procurement group did not choose Nova for a Technology Breakthrough Award.

### B. A Conflict Of Interest Arises Out Of The 3% Fees That GPOs Collect.

GPOs have an incentive to make decisions on behalf of hospitals based on which suppliers give them the biggest fees. For this reason, they may choose the higher priced product – even though it may not be in the best interest of their participating hospitals and, ultimately, of patients and taxpayers.

Although GPOs should have a fiduciary duty to their participating hospitals, the suppliers pay them. Decisions concerning the relative merits of products often become secondary to the GPO fee structure. GPO contracting decisions are biased by the larger GPO fees paid by incumbent suppliers, particularly when capital equipment items require substantial purchases of supplies following the equipment purchase.

The consumables required for the operation of blood gas analyzers illustrate how decisions about contract awards may be influenced by fee considerations. Premier does not make separate contracts for blood gas analyzers and the requisite consumables, because each manufacturer is the only source for the related consumables. Because Nova has always been excluded from a Premier contract and Bayer has been an incumbent since 1997, Bayer has a much larger consumable trail from their older blood gas analyzers within Premier hospitals. Even though Nova has newer technology and more breadth of blood gas analyzer models, Bayer's GPO fees paid to Premier are much greater than would be Nova's due to this higher consumable trail from Bayer analyzers already in the Premier system.

As a result, Premier will generate substantially higher fee income by contracting with Bayer instead of with Nova for a new blood gas equipment award. For example, if every Premier hospital (1500) purchases one blood gas analyzer from Bayer instead of Nova, these hospitals will have spent about an extra $53 million over the three-year contract period. That is, each hospital must spend $35,547 more per analyzer to purchase and operate Bayer's blood gas analyzer equipment versus Nova. The difference in equipment and consumable costs means that Premier would obtain $4,045,000 in fees if each hospital purchased one Bayer analyzer and consumables over three years versus $2,541,000 from Nova's equipment and consumables' sales. (This hypothetical is based on the contract pricing offered by Bayer and Nova as a base price for their blood gas analyzer equipment plus the estimated requisite consumables to operate the equipment over three years and is calculated as shown in Exhibit 1 to this letter).

If Nova competes again with Bayer in 2005 (after they have held the contract for nine years and Nova zero), the process will be further biased toward the incumbent who will then be paying Premier even higher fees based on an even larger installed base. At that point there will be an even greater incentive to choose Bayer, regardless of relative product quality, because their fees on consumables from older analyzers to Premier could be three to four times the Nova fees.

### C. Some GPO Contracts Are Exclusionary, Reduce Competition Among Suppliers Of Health Care Products And Services And Do Not Provide The Lowest Price For GPO Members.

The most intense competition for blood gas analyzers occurs at individual hospital sites or integrated delivery networks (IDNs) when a sale is imminent and all five blood gas vendors are allowed to compete at the point of sale, not out of the "one price fits all" pricing schedules that are negotiated in the past and at a distance by GPOs. The current Premier blood gas contractors submit bids and sell analyzers at lower prices than their Premier contract pricing to non-Premier hospitals when they are forced to be price competitive with four other blood gas vendors in a non-restricted sale.

Since blood gas analyzers generally have a product life of 4-6 years, each equipment sale is very important to the manufacturer. Given the strong competition in the "open" (non-GPO) market, all hospitals -- no matter what size -- can buy capital equipment on the open market at better pricing than what they are offered through a Premier contract. The notion that small 50 bed hospitals must purchase through a GPO to get the best volume discount prices on capital equipment is simply not correct.

Below are some recent examples of Bayer's sales of blood gas analyzers to non-GPO customers who have independently obtained pricing that is far superior to the Bayer pricing that Premier offers to their 1500 participating hospitals. In fact, the indicated disparity in pricing is even more remarkable because these hospitals bought newer model analyzers bearing higher list prices than the older equipment offered by Premier:

| | Hospital | Premier GPO | Model | Quantity | Bayer Price to Non-GPO Customer | Bayer Contract Price To Premier* | Date |
|---|---|---|---|---|---|---|---|
| 1 | Randolph, VT | No | Rapidpoint 405 | 1 | No charge | $21,660 ea | Oct, 2003 |
| 2 | Atlantis, FL | No | Rapidpoint 405 | 3 | 12,666 ea | $19,927 ea | Sep, 2003 |
| 3 | Philadelphia, PA | No | Rapidpoint 405 | 4 | 14,500 ea | $19,927 ea | Jun, 2003 |
| 4 | Medford, OR | No | Rapidpoint 405 | 2 | 14,500 ea | $19,927 ea | Mar, 2003 |
| 5 | Raleigh, NC | No | Rapidpoint 405 | 4 | 13,000 ea | $19,927 ea | Mar, 2003 |
| 6 | Los Angeles, CA | No | Rapidpoint 405 | 2 | 15,000 ea | $19,927 ea | Nov, 2002 |

* The prices listed were obtained from Bayer's 2001 Premier list and relate to the Rapidpoint 400, which is an older model than the Rapidpoint 405 sold to the above non-GPO hospitals. The Bayer pricing data would be applicable to all purchases made by Premier hospitals at the same time as the above sales and reflect Bayer's quantity discounts.

### D. GPOs Block The Flow Of New And Innovative Products From Smaller, Non-Contract Companies Such As Nova Into Their Hospitals.

GPO member hospitals must overcome substantial hurdles before being able to purchase goods or equipment from suppliers not on the GPO list. For example, in order to get an exemption for equipment a hospital must first show that it has evaluated products on the Premier approval list and found them inadequate. The purchasing department must then get the written approval of the hospital's chief executive officer and provide a rationale to Premier for why it needs the features of the products it prefers. This process alone takes considerable time, which in and of itself constitutes a substantial disincentive for considering other options. Moreover, even after going through this process, Premier still can and does arbitrarily reject these exemptions and takes extended periods of time before making a decision. Premier's "Code of Conduct" has not made it easier for hospitals to obtain exemptions. There remain neither objective standards nor a time frame for obtaining such exemptions.

Even if hospitals are able to obtain an exemption, the fear of losing rebates if the hospital does not meet the GPO's compliance levels (in some cases as high as 90-95%) serves as a great disincentive. The fact that Nova has a market share of 11% amongst Premier hospitals despite these burdensome hurdles indicates the superiority of our equipment.

The length and exclusionary nature of GPO contracts also stifle innovation. Nova has been the clear technology leader in expanding the test menu and the clinical utility of blood gas analyzers. By contrast, the blood analyzer models these large GPOs have made available to their participating hospitals were introduced as early as the 1980s compared to the late 1990s through 2002 for Nova. Notwithstanding this fact and despite repeated efforts, Nova has been unable to sell through these large GPOs. In addition, the length of the GPO contract awards precludes hospitals from obtaining access to new technology in any effective span of time.

### E. The 3% GPO Fees Are Excessive, Redundant, Costly To Consumers And Payers And Lead To Abuses.

Premier's net income of $205,000,000 based on GPO fees of $392,000,000 gives them a profit margin far larger than most hospitals or medical device manufacturers. Premier has a far more profitable operation than pharmaceutical companies who are being pressured to reduce drug costs.

GPOs do not eliminate purchasing departments and related costs already being maintained by hospitals or IDNs themselves. In fact, the 3% GPO fees are largely redundant with purchasing staff and activities at each hospital. Capital equipment purchases particularly require that hospitals spend significant resources in order to pick the equipment best suited for the individual needs of hospitals. This effort typically involves product demonstrations, evaluations, product comparisons, site visits, and vendor meetings. Hospitals purchasing through GPO contracts must still conduct evaluations of the equipment but are limited in model choices and pay higher equipment costs.

### F. Because Of Widely Disparate Hospital Needs, GPO Restrictions On Available Equipment Impair Care And Create Unnecessary Costs.

U.S. hospitals are extraordinarily diverse and specialized. Hospitals range in size from 25 beds to over 1,000 beds. Their missions and medical specialties can range from labor and delivery, orthopedics, cardiac surgery, cancer, neonatal intensive care, transplant surgery, EENT (eye, ear, nose and throat), burn care, rehabilitation, to trauma among others. This creates significant differences including different medical technology needs among hospitals. Additional hospital differences are created by the different patient populations that a hospital may serve such as urban, rural, geriatric, women's, pediatric, acute, sub-acute and tertiary. Hospitals also differ in their physical infrastructure, operating budgets, capital budgets and reimbursement rates. All of these differences create the need for a wide variety of medical technology equipment, functions and pricing in order for all these different hospitals to efficiently and effectively accomplish their widely differing missions.

As a result of the diverse medical technology needs of U.S. hospitals, different medical equipment manufacturers have become specialized in their product offerings. Many capital equipment manufacturers of specialized medical technology equipment such as blood gas analyzers, ventilators, patient monitors, and blood chemistry analyzers have important differences in the features of their product compared to their competitors. Many small capital equipment manufacturers specialize in equipment that is designed for only one segment of the diverse hospital market.

Despite this extraordinary complexity of hospital needs and medical technology choices, Premier has made a limited "one size fits all" selection of choices of sophisticated, critical care diagnostic analyzers available to all 1500 hospitals. In 2001, Premier's purchasing staff awarded blood gas analyzer contracts to Bayer Diagnostics and Instrumentation Laboratories who each had only 5 models to address the diverse needs of 1500 hospitals. This award was made despite the fact that a technical evaluation committee from Premier hospitals was about to recommend that a contract award be made to Nova. After initially choosing only these two, Premier added a third supplier, but still severely limits the choices available. The technical evaluation committee chose Nova in part because of a recognition that Nova had the most blood gas models (11), the most blood gas features/performance/price ranges and the most test menu choices. The exclusion of Nova forced participating hospitals into limited choices and foreclosed them from choices that might well have been more appropriate for the needs of their institution, as the following chart indicates:

| Vendor | Number of Models | Price Range of Models to Premier | Available Test Menu |
|---|---|---|---|
| Nova | 11 | $9500-40,887 | 3-20 Tests |
| Bayer | 5 | $18,602-36,244 | 3-13 Tests |
| IL | 5 | $15,000-51,000 | 3-14 Tests |

In the case of Premier's 2003 contract selection of blood gas analyzers all these decisions were apparently made by GPO contracting personnel, not by hospital medical, laboratory, engineering or financial staff. Contracting personnel are not expert in the range of hospital considerations. However, with total authority, they would naturally focus on maximizing GPO fees, rather than paying primary attention to the needs of the patients and hospitals.

## II. The General Services Administration Model Addresses the Anti-Competitive Practices of GPOs

Nova strongly urges the FTC and DOJ to consider existing precedent for the Government's purchase of goods by contrast to the manner by which GPOs today contract for goods in order to retain their antitrust exemption. The General Services Administration ("GSA") model provides a solution to problems that GPOs have caused and could be especially beneficial to hospitals purchasing capital equipment. We believe that all manufacturers who can satisfy an initial quality screening should be allowed to compete for hospital business. An open marketplace encourages innovation, drives down prices and gives hospitals and patients access to the best technology. The GSA model offers the following benefits:

1. **GSA Federal Supply Schedules are not exclusionary and provide for aggressive discounts.** GSA invites all vendors to participate in receiving a GSA contract. Each vendor provides a discounted contract price to GSA that represents the maximum price charged by the vendor. Vendors are then encouraged to discount further at the point of sale. For example, Veteran's Integrated Service Networks (VISNs) who choose to standardize on a single vendor typically invite four or more supply schedule vendors to participate in the competition and thus gain even better prices and terms.

2. **GSA Federal Supply Schedules do not inhibit the flow of new technology from smaller companies.** Any vendor that meets a minimum test of commerciality is allowed to participate in a GSA contract. This provides an opportunity for new technology from smaller companies to enter the market.

3. **GSA Federal Supply Schedules enhance competition by allowing multiple vendors to compete at the actual point of sale**. The most competitive pricing occurs at the actual point of sale when multiple vendors are competing. As a result, the prices that individual VA Hospitals and VISNs can negotiate are more favorable than GPO customers buying in similar quantities.

4. **GSA 1.5% Industrial Funding Fee is affordable and not excessive**. Because the GSA fees are substantially less than GPO fees, there is less overhead added to vendor's cost and more savings to pass on directly to the customer. Since all vendors are invited to participate in GSA contracts, there is no bias toward a manufacturer based on their fee payments.

5. **GSA Federal Supply Schedule contracts eliminate the bias toward incumbent suppliers of capital equipment items**. The GSA separates capital equipment contracts from the associated supplies contracts. This eliminates the substantial GPO fee advantage incumbent suppliers enjoy when capital equipment and supplies are bundled into the same GPO contract.

6. **The GSA Federal Supply Schedule guarantees the best pricing to its members.** No vendor is permitted to sell at lower prices to non-GSA purchasers who are within a specified buyer category and who purchase in similar quantities and terms. Any vendor who sells at more favorable terms or prices must offer the same terms and prices to GSA purchasers. This provision eliminates the Premier GPO contracting fee bias toward awarding higher pricing than can be obtained in the open market.

We appreciate both the FTC and DOJ's continued attention to these important matters. Nova Biomedical strongly believes that the GPO's own efforts to self-regulate have not improved their anti-competitive contracting practices. Strong reforms are necessary to bring about fundamental change in the way some GPOs operate. Please contact us if we can provide any further information or assistance.

Sincerely,

Howard Deahr

Howard Deahr

Vice President Sales, North America

cc: Susan Pettee, Esq.

**Premier Hospital Contract Pricing Comparison**
**Nova State Profile pHOx v Bayer Rapidpoint 400**

**Instrument Cost**[1]

| | Bayer Rapidpoint 400 | Nova Stat Profile pHOx Plus | Nova Savings | Nova % Savings |
|---|---|---|---|---|
| Base Price per Order Per Hospital | 21,660 | 18,560 | 3,100 | 14.3% |
| 2-5 Units | 19,927 | 17,980 | 1,947 | 9.7% |
| 6-10 Units | 17,934 | 16,820 | 1,114 | 6.2% |
| 11-15 Units | 15,962 | 15,950 | 12 | Even |

**Consumable Cost**[2]

| | | | | |
|---|---|---|---|---|
| Annual Cost of Consumables at 15 Samples per day | 22,750 | 12,631 | 10,119 | 44.5% |

[1] Purchased once every 4-6 years
[2] Purchased every year

## What Premier Would Lose by Contracting with Nova's Lower Prices Over A Three-Year Contract

A hospital buys one analyzer from Bayer:

| | | |
|---|---|---|
| Instrument Cost | Year 1 | $21,660 |
| Consumable Cost | Year 1 | $22,750 |
| | Year 2 | $22,750 |
| | Year 3 | $22,750 |
| Total Cost to Hospital: | | $89,910 |
| Premier Fee (3%) | | $2,697 |

A hospital buys one analyzer from Nova:

| | | |
|---|---|---|
| Instrument Cost | Year 1 | $18,560 |
| Consumable Cost | Year 1 | $12,631 |
| | Year 2 | $12,631 |
| | Year 3 | $12,631 |
| Total Cost to Hospital: | | $54,453 |
| Premier Fee (3%) | | $1,694 |

If every Premier hospital (1500) bought one analyzer, Premier Inc would lose $1,504,500 more by giving a contract to Nova rather than Bayer. However, each hospital would have to spend $35,457 more to purchase a Bayer versus Nova. The total cost of the Bayer contract to the 1500 hospitals is $53,185,500 over the three-year contract.