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Founder & CEO of Masimo Corp.

Before the Antitrust, Business Rights and Competition
Subcommittee of the US Senate Judiciary Committee

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Chairman DeWine, Ranking Member Kohl and Committee Members, thank you for inviting me to speak here today as the CEO of a medical technology company, Masimo and as a Board Member of the Medical Device Manufacturers Association. As a Board Member, I have also been asked to speak on behalf of the hundreds of medical technology companies who continue to face barriers in accessing the hospital marketplace.

Two years ago, I testified before this Committee about the anticompetitive practices of certain GPOs and their collusion with the incumbent dominant suppliers. These practices included the bundling of unrelated products, the enforcement of long -term sole-source contracts, the payment of excessive fees from the dominant suppliers and other clear conflicts of interest.

After the hearing, I had the opportunity to meet with Senator Kohl, and during that discussion, Senator Kohl asked me, "what do you think, do we need legislation? I replied, "Hopefully not. Let's see how the code of conduct works." Well it's been over two years since then, and I can tell you that for the most part, it hasn't worked and in the absence of oversight, it will get worse. As a result, I believe that oversight is required if patients and caregivers are to have access to the innovative medical technologies they deserve.

Although progress has been made in some areas--due largely to the persistent efforts of this Committee--both the industry code of conduct and the individual GPO codes do not adequately address many of the anticompetitive contracting practices that have denied patients and caregivers access to innovative technology and have increased the cost of health care. In addition, some of the codes have not been implemented in a timely, honest and effective manner. Finally, hospitals, and the federal government in its role as a primary funder of health care services, are continuing to pay more than they should for effective health care products and medical devices, because of these types of anticompetitive practices.

Without passage of the legislation, which would provide the authority and oversight for permanent, comprehensive and verifiable reforms to ensure competition and access to most effective health care, not only will the situation not improve, but the GPOs will likely revert back to their old ways once the Senate spotlight has faded. Unfortunately, patients, medical innovations and providers of health care will then be the victims.

As you may recall, my company, Masimo Corporation, has developed the first read-through motion and low perfusion pulse oximetry, often described in the industry as Next Generation pulse oximetry. A pulse oximeter is the non-invasive monitor used to measure oxygen in the blood. This is important because if your blood oxygen level drops below normal, within three minutes brain damage can occur and within five minutes you can die. With babies there is the additional problem of too much oxygen in the blood. If this occurs, the baby can get serious eye damage, and go blind. Approximately 12% of the babies in the Neonatal Intensive Care Units are affected by this each year. Before the advent of our technology, pulse oximeters gave false alarms nine out of ten times and did not work in the most critical times.

Our technology has been clinically proven to be much more accurate and reliable than the previous generation, which many clinicians have concluded should lead to improved patient care. In fact, since I last testified, a landmark study was published on data collected over five years at Cedars Sinai Hospital in Los Angeles. That study concluded that a neonatal eye disease, called ROP, could be virtually eliminated through the use of a new oxygen management protocol utilizing our technology. (Exhibit 1) So, at the very least, you should know that your efforts and the past hearings you have held, probably saved the eyesight of countless premature babies.

Another important study was published by researchers from the University of Virginia that examined the impact of our improved performance on caregiver effectiveness. That study concluded that the use of Masimo SET improved caregiver effectiveness, resulting in positive impacts on caregivers and patient outcomes. The researchers suggested that these improvements could lead to reduced medical errors. (Exhibit 1)

You may remember that at the time of the first hearing, Masimo had been denied contracts from most of the nation's GPOs, including the two largest, Novation and Premier. This was in spite of the fact that there had been over 50 clinical studies by independent researchers around the world that proved that Masimo's technology was indeed superior -- by improving care and reducing costs. It was determined, by Premier's technology assessment group, that Masimo Set could be considered a "Breakthrough" and put on contract. Yet, we were not awarded a contract at that time.

Thanks to this Committee and its efforts, Premier reviewed our technology a second time and ultimately changed the contract from a sole-source to a multi source contract and eliminated their bundling contract with Tyco; thereby including Masimo. Since then, we have been making progress in selling to Premier hospitals, offering their members better technology at a lower cost than the incumbent supplier, Tyco-Nellcor. We have seen our annual sales to Premier members increase more than tenfold, with 39 Premier hospitals converting hospital wide to our pulse oximeters. As you may recall, prior to your intervention, I testified at the 2002 Senate Hearing, that not even one Premier hospital had converted to Masimo SET hospital-wide, despite the fact that many Premier member hospitals had shown great interest in acquiring our pulse oximetry technology and had purchased up to their 10% limit, decreed by the GPOs and Tyco. Although Premier has

made some changes for the better, we have heard that Premier is considering reverting back to sole source contracting practices.

With Novation, the market leader, things have not been as positive since your hearings and the voluntary codes of conduct. Although Novation claimed to be nothing more than agents for the hospitals, their actions indicate they are generally agents for the dominant suppliers. First, it was not until the eve of this Committee's second hearing that Novation opened up it's sole-source contract and awarded us a contract for pulse oximeters. Novation even argued that pulse oximetry was not a "clinical preference" item, contrary to all of the literature, and the fact that pulse oximeters have to be prescribed by doctors. But thanks to your second hearing, Novation changed its mind and put us on contract. And although Novation claimed at that time that they were going to be a "neutral middleman" and their members were free to choose either product, Novation continued to actively promote the dominant supplier's product over ours and attempted to lock in their member hospitals to Tyco pulse oximetry immediately before Tyco's key pulse oximetry sensor patents were to expire.

I would like to show you an excerpt from a letter that was sent out by Novation in the third quarter of 2003, right around the same time that Masimo was awarded a contract and we were told that we would be competing on a level playing field. As you can see, it asks their member hospitals to re-commit to buying Tyco's pulse oximeters and participate in the bundle. (Figure 1)

I was shocked when I saw this. It clearly contradicts what Novation has said about being neutral and being agents for hospitals. You may be interested to know that Novation refused to discontinue their bundling program, as Premier did. Instead, Novation agreed, at our insistence, to let hospitals opt out of the pulse oximetry piece, if hospitals wanted to buy Masimo instead of Tyco's pulse oximeters. We thought this meant that the hospital would be allowed to buy Masimo pulse oximetry without losing their bundling rebates on the other 11 products in the Novation bundle program. So when we saw this notice to the hospitals from Novation, we realized how disingenuous Novation was to us, to their member hospitals and their own code of conduct. At the same time that Novation was insisting on its neutrality, they sent a letter asking for their members to recommit to include Tyco pulse oximetry in the bundle. This behavior is duplicitous and not in the best interest of hospitals or, health care and is a clear example why the codes of conduct are not sufficient to reform the GPO industry.

What is even more troubling about Novation's actions was that they were pushing a product that would cost their member hospitals more than they would otherwise have to pay. As I explained earlier, a key patent was set to expire on Tyco's sensors soon after Novation sent out this re-commitment letter. In fact, the deadline imposed by Novation in the letter to recommit, October 31, 2003, was only a couple of weeks before Tyco's patent expiration in November of 2003. (Figure 2) I am sure everyone, let alone this committee, can appreciate what generic products can do to reduce costs for patients and hospitals. Many companies were waiting in the wings ready to provide a generic sensor

at a great savings, but this letter thwarted generic sensor sales in Novation hospitals. I hope this letter can be made a part of the record here today. (Exhibit 2)

As this example indicates, GPOs have often acted as an agent to the suppliers, rather than their member hospitals. Otherwise, why would they favor a more costly product for their member hospitals? The only logical conclusion is because it generates more revenues for the GPOs, since their earnings are largely based on a percentage of a product's total contract price. This type of conduct by Novation, the nation's largest GPO, is very troubling – especially in this era of rising health care costs.

The GPOs have stated that forcing them to abandon their sole source contracts and bundling programs would end up in higher prices being charged to their members. Our experience has proven the opposite. We have converted over 100 hospitals, both large urban hospitals and small rural hospitals, from Tyco to Masimo and have provided those hospitals substantial savings over what they were previously paying under the sole source contract pricing. We would be happy to provide to the Committee a confidential list of those hospitals.

While Premier and Novation have been the primary focus of this Committee's attention, it is important that reforms are applied uniformly. Several of the GPOs have submitted codes of conduct to this Committee, but some of them have taken advantage of the fact that they are lower profile. One example of that is MedAssets, now the third largest GPO. In fact, MedAssets CEO often cites that his company had been the biggest beneficiary of the NY Times articles and the Senate Investigations since many of the members of Premier and Novation who did not want to be associated with Premier and Novation any longer had moved their business to MedAssets. MedAssets claims to now represent $10 Billion of US hospital products purchases. In contrast, prior to the first Senate Hearing, NY Times published that Novation and Premier represented $19 Billion and $14 Billion of the hospital purchases, respectively. MedAssets is no longer a small GPO.

MedAssets awarded Masimo a multi source contract just before last year's hearing and we were told that we had an equal opportunity to compete. Earlier this year, we started getting reports from our sales people that certain MedAssets accounts couldn't afford to purchase and wouldn't even evaluate our products due to rebates that they would lose in the Select Program. Select is a program structured very similarly to Novation's Opportunity Program in that it ties rebates based on the purchase of a bundle of unrelated products from different suppliers—and to receive the rebates, a hospital must purchase at least 90% of the products in every product category of the program. (Exhibit 3)

Currently Tyco has multiple products in the "Select Program", including pulse oximetry. Therefore, if a member hospital were to purchase only 89% of their pulse oximetry products from Tyco and 11% from Masimo, the member would lose all of their rebates, not only on pulse oximetry products, but on all other Tyco products and on all products from all other manufacturers they purchase through the "Select Program". This lost

rebate can easily be worth more than the member's entire purchases of pulse oximetry products.

MedAssets' code of conduct, which was introduced in February of last year specifically stated that they would not bundle clinical preference products with any other unrelated products. The Select bundling program is a direct violation of that code of conduct.

When I confronted the CEO of MedAssets with the Select program, instead of him saying he planned to discontinue it, we were invited to take part in it. After reviewing the program and seeing that it indeed was what we thought it was; it bundled clinical preference products even more onerously than the Novation Bundle program, we refused to bid. We sent a no-bid with an explanation to why we refused to bid. MedAssets response was the usual "our members want it, it's voluntary, …", and something new: that the staff of this Committee had blessed it, which I seriously doubt.

On their web site, we noticed that MedAssets had modified its code of conduct in October 2003 and no longer stated that they would not bundle. In fact, their current code is silent on most practices questioned by this Committee. What is happening at MedAssets is a great example of why there needs to be lasting reforms which are equally applied. MedAssets could become the biggest GPO in less than 3 years from the date that Premier & Novation were asked to come up with codes of conduct that would eliminate their anti-competitive practices, such as bundling and sole source contracting. Yet, MedAssets, not being under the microscope never stopped their bundling program which they promised they would do in February 2003 and now over a year later feel that they can unilaterally modify their code of conduct. (Exhibit 3A)

Absent the establishment of ongoing oversight, we are very concerned about what will happen when this Committee focuses on other pressing issues. Unfortunately, the problems that Masimo has been experiencing are not very different from what hundreds of other companies are going through. I understand that the Medical Device Manufacturers Association (MDMA) provided the Committee with nearly 20 key examples, affecting thousands of contracts, of the sorts of problems that, unfortunately, have not been corrected by the codes of conduct. These still include examples of the bundling of products from unrelated companies, the bundling of unrelated products, sole-source agreements, the charging of excessive fees, high commitment level contracts and requiring vendors to participate in outside business ventures. Unfortunately, companies like Applied Medical, Retractable Technologies, Nova Biomedical, Rochester Medical, Adroit Medical, Pevco and many others are still facing serious barriers to the marketplace. Like Masimo, some of these companies have been granted "token" contracts by some of the GPOs or no contract at all. These are situations similar to what I have described above with Novation and MedAssets where we were put on contract while at the same time the GPO favors and promotes the incumbent dominant vendor's products through promotions and active bundling programs. I would characterize the majority of our GPO contracts in this way.

Additional manufacturers and healthcare workers are extremely concerned about the anticompetitive practices of certain GPOs and are calling for reform, but need to do so anonymously because of a real fear of retribution. If there is any doubt, let me quote from an email sent to me by Jim Fitzgerald, the CEO of HealthTrust, one of the leading GPOs. HealthTrust had put us on contract prior to this Committee's initial hearing, but Mr. Fitzgerald was not happy that we chose to speak out and push for GPO reforms, and specifically legislation proposed in California to deal with these same issues. In his email he said, "As our President says, you are either with us or against us in our fight against terrorism. You decide what side of the fight you are on. I will know by your support of this legislation." (Figure 3/ Exhibit 4)

After our testimony, the HealthTrust management along with Tyco were reportedly active in derailing any hospital negotiations Masimo was involved in with their members. And, shortly after this email, we were informed that our contract, which had been a "token" contract, would not be renewed. HealthTrust now has a sole source contract with Tyco for pulse oximeters. In addition to this example, we have heard numerous comments through friends in the industry that GPO representatives are saying that Masimo "upset a lot of people" and that Masimo, along with other smaller vendors, were added to their contracts only because of the oversight activities of this Committee. They are also pledging to move back towards sole-source contracts once the Senate light is off of them.

I am not one to trumpet more legislation over less, but the situation here is different. The problems that we are talking about today were caused by the legislation that gave GPOs safe harbors from the anti-kickback statutes. The dominant vendors found that exclusionary GPO contracts could be a very powerful arsenal in their monopolistic quests. The dominant vendors could control the GPOs by offering large payments in exchange for exclusivity. Not only do the GPOs help the largest vendors keep competition out, by not awarding contracts to competitors and building multi-level bundling roadblocks, but the GPOs even waste millions of dollars of what might be taxpayer's money each year actively promoting those dominant vendors' products through GPO salesmen. There really is a fatal flaw in the current system that can only be fixed with legislation and permanent oversight.

Medical technology and biotechnology companies are regulated by the FDA to help ensure that the quality and efficacy of medical products meet established standards. Because of their unique advantage granted through their exemptions to the anti-kickback statutes, GPOs have become the gatekeepers of which products get purchased and which companies ultimately survive. It seems entirely inconsistent to grant any group this kind of power and potential impact on public health without any persistent oversight to ensure that the public is being served and not harmed by the power granted to them.

Despite what you may hear from others in the industry, the only parties worse off from this legislation will be the large vendors who have been benefiting from their purchased exclusivity and the GPO executives, some who have personally benefited millions from their powerful positions as gatekeepers. Certainly, hospitals and their patients will be better off because real competition will be restored to the marketplace, which will result

in lower prices and better products. The GPOs as a whole will be better off because they will no longer be subject to the pressure exerted by the largest vendors who threaten to take their fees away if they don't get the exclusionary contracts they want. At last year's hearing, Premier's CEO, Richard Norling, stated that many of the controversial practices were at the insistence of the vendors. He seemed to be asking for your help. This legislation would give the GPOs more leverage with the vendors because they would be prohibited from granting such contracts.

For the wellbeing of patients, clinicians, and innovation, please do not take your oversight away from this issue without enacting this legislation. Without your leadership and oversight, I am certain no progress would have been made over the past few years, even for Masimo. However, I hope that you will agree that the examples I have provided indicate that problems still exist in the health care field regarding the GPOs, and therefore, further action is needed. The draft legislation is needed to allow the hundreds of innovative companies -- that have not had the opportunity to testify before the US Senate – to compete fairly in the health care arena. I firmly believe, that, but for the oversight by this committee together with my company's vigorous efforts to provide a better product at a better price, many patients would still not have access to Masimo's breakthrough, cost-effective pulse oximeters.

This legislation would provide the opportunity for additional oversight to ensure that clinicians have access to the best technology and that EVERY company making effective products, competitively priced, is given a chance to compete and sell to hospitals through a GPO, not just the dominant suppliers or those who testify before a Senate Committee.

I urge you to enact this discussion legislation, which will provide the necessary framework for steady oversight of the GPO marketplace. This legislation will benefit people across America. Again, I want to thank everyone on this Committee for all your efforts to infuse competition back into the hospital marketplace.

Novation Member Reconfirmation Form
Seller: Nellcor Puritan Bennett
Products: Pulse Oximetry Products

Volume & Participation

The undersigned Novation Member (as defined in the above Agreement) reconfirms, as of ___, 2003 (a date that must be no later than October 31, 2003), that it intends to continue at its current commitment level of either ≥ 95%, or ≥ 75% but <95% until the expiration date of the above referenced Agreement, in exchange for which Nellcor Puritan Bennett Incorporated ("Seller") will provide the below referenced pricing as appropriate for commitment level and volume.

Figure 1

Novation Timeline

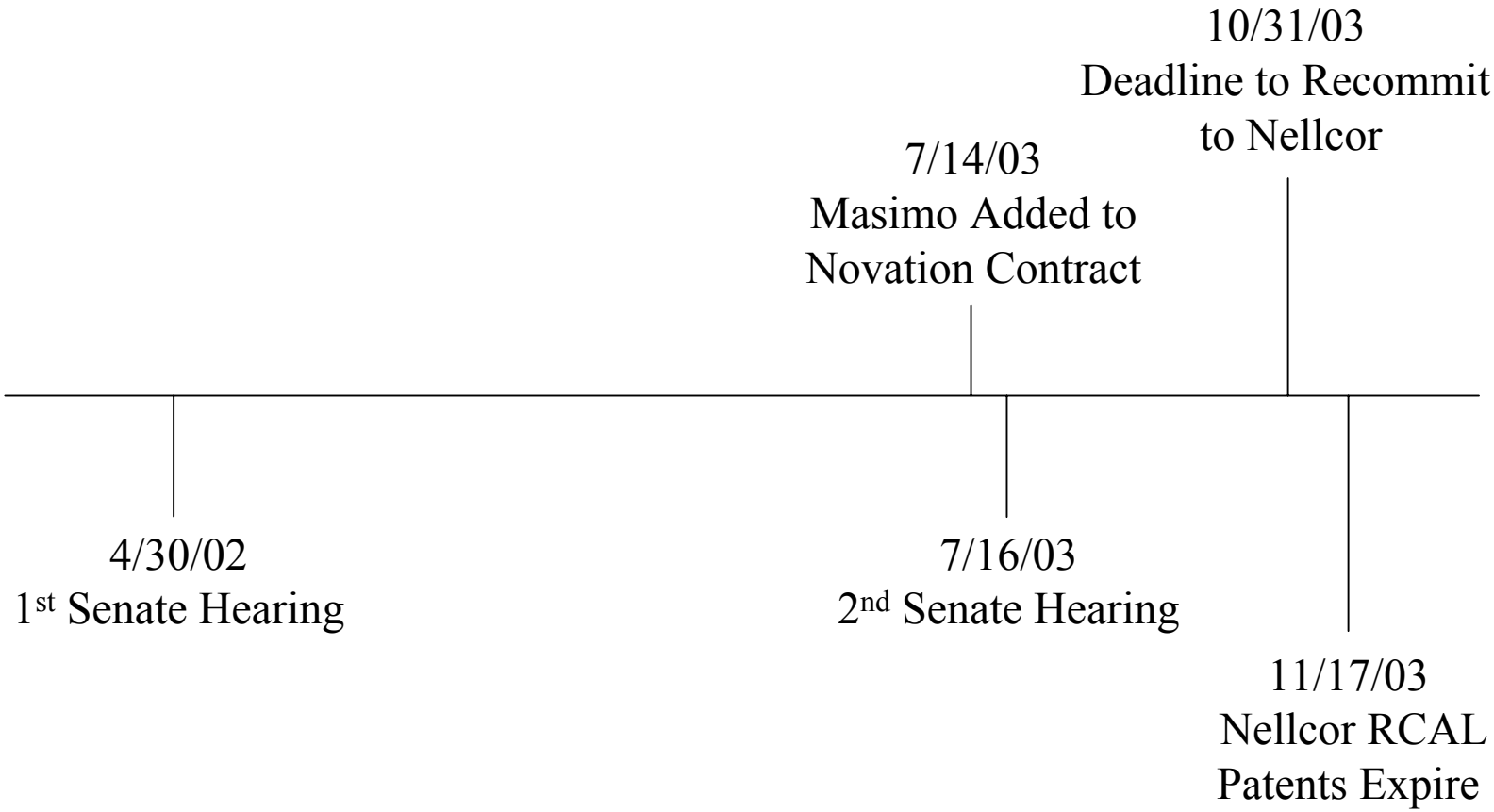

Figure 2

"As our President says you are either for us or against us in our fight against terrorism. You decide what side of the fight you are on. I will know by your support of this legislation."

-*Jim Fitzgerald, CEO of HealthTrust*

June 3, 2003

Figure 3