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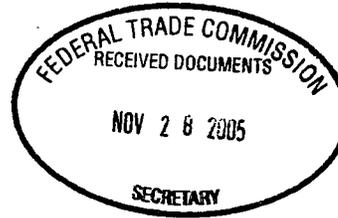
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ORIGINAL

November 28, 2005

BY HAND DELIVERY

Federal Trade Commission  
Office of the Secretary, Room 135-H,  
600 Pennsylvania Ave., NW.,  
Washington, D.C. 20580



Re: In the Matter of Johnson & Johnson, Inc. (File No. 051-0050)

Dear Mr. Clark:

Medtronic Vascular, Inc. ("Medtronic") hereby submits its comments to the proposed Consent Order in the above-captioned matter. These comments are intended to help ensure that the proposed Consent Order accomplishes its remedial purpose of maintaining competition.

## Background

As the Commission is well aware, the U.S. drug-eluting stent ("DES") market is presently a duopoly shared by Johnson & Johnson, Inc. ("J&J") and Boston Scientific Corporation ("Boston Scientific"). Guidant Corporation represented the next positioned company to enter the DES product market using rapid exchange ("RX") stent delivery technology as do J&J and Boston Scientific. The Commission concluded that "[t]he proposed acquisition would cause significant competitive harm in the market for DESs by eliminating Guidant as the only potential competitor with the ability to offer a DES on an RX delivery system. As a third RX entrant into the DES market, Guidant likely would increase competition and reduce prices for DESs." (*See Analysis of Agreement Containing Consent Order to Aid Public Comment at 3*) (hereafter "Analysis.")

Given this conclusion, the Commission must do all that it can to ensure its proposed Decision & Order ("D&O") fully maintains competition in this critical healthcare market. To do anything less will deprive physicians and patients of having a strong, competitive third option that would provide new entry into the DES market at the same time that Guidant would have entered the market had it remained independent. Indeed, should the Commission's remedy fail to maintain competition, higher healthcare costs, reduced innovation, and poorer patient outcomes will result.

In the following pages, Medtronic proposes specific modifications to the proposed D&O that will increase the likelihood that the order will accomplish the Commission's remedial purpose of maintaining competition in the DES market. Accordingly, Medtronic urges the Commission to

adopt these recommendations and modify its proposed D&O to best serve the interests of the physicians and patients who rely on these life-saving medical devices.

### **The Proposed Decision and Order**

As presently drafted, the D&O requires J&J to license its DES patents to Abbott Laboratories (“Abbott”). (*See* D&O Art.II.A.) This represents a departure from the Commission’s usual requirement of a divestiture of “an autonomous, on-going business unit of one of the parties to the merger” to maintain competition. *See* Statement of the Federal Trade Commission’s Bureau of Competition on Negotiating Merger Remedies (Apr. 2, 2003). Rather than requiring J&J to divest its Cordis interventional cardiology unit or Guidant’s interventional cardiology business, the Commission proposes to accept a remedy consisting of a license of intellectual property to facilitate entry into the DES market.

The Commission noted that its staff “concluded that Abbott was among the companies well-positioned to replicate the competitive impact Guidant was likely to have absent the proposed acquisition.” (*See* Analysis at 3.) The Commission further concluded that “Abbott, therefore, is poised to become a strong competitor in the DES market when it enters in the second half of 2007, approximately the same time as Guidant’s anticipated date of entry. Access to the RX delivery system will allow Abbott to replace Guidant as the third entrant into the DES market with an RX delivery system.” (*Id.*)

### **The Need for Modification**

If Abbott fails to enter the DES market by 2007, as the Commission's order anticipates, the proposed D&O needs additional safeguards to protect the interests of physicians and patients. Simply giving Abbott the ability without the obligation to transfer its license to J&J’s DES patents if its own DES program fails to succeed does not adequately protect competition. (*See id.* at 4.) To protect competition, the Commission's order must also contain a mechanism to ensure that if Abbott fails to enter the DES market by 2007, the license will be transferred to another company that is able to enter the market promptly.

An entrant into the DES market, like Abbott, faces significant hurdles to succeeding in bringing a DES product to market. As the Commission’s Complaint alleges, barriers to entry into the DES market are high. (Compl. ¶20.) Even experienced stent manufacturers encounter obstacles in developing these complex and delicate devices, obtaining the necessary approvals from the Food and Drug Administration (“FDA”), and commercializing these devices. Indeed, a senior Abbott executive recently said that Abbott now expects FDA approval for its DES product will be delayed until 2008 due to slow enrollment in its DES clinical trial. Thomson StreetEvents, *ABT-Q3 2005 Earnings Conference Call Preliminary Tr.* (Oct. 19, 2005) (comments of R. Gonzales, Pres. & COO, Abbott Med. Prods. Group) (attached as Appendix 1). For these reasons, Medtronic proposes the following modifications which, if adopted, will increase the likelihood that the objectives of the Commission’s Consent Order will be achieved.

### **Recommended Modifications**

Usually, in its consent orders requiring licensing of intellectual property in the health care field, the Commission includes provisions to protect competition in the event that the proposed licensing remedy fails. The proposed order in this case contains no such safeguards for DES competition if Abbott should fail to develop a product to compete with those of the incumbent firms. For example, the proposed order contains no provision for cancellation of the divestiture license and subsequent licensing to another in case Abbott fails to develop a product. Such provisions are common in previous orders of the Commission requiring licensing of intellectual property, and there is no apparent reason for their exclusion from the proposed order.

To mitigate the risks that the license agreement in the proposed D&O will fail to achieve the remedial purposes of the Commission's order and result in harm to competition, Medtronic recommends that the Commission modify the proposed order. Specifically, the Commission should: (1) appoint a Monitor Trustee to oversee Abbott's efforts to develop its DES product using the DES patent license and associated know-how, (2) adopt objective, impartial criteria to evaluate the likelihood of Abbott actually entering the DES market by the second-half of 2007, and (3) allow for the appointment of a Divestiture Trustee to transfer the DES patent license to another Commission approved licensee if Abbott fails to meet the criteria for likely entering by the second-half of 2007.

These measures mitigate the risks that arise from relying upon a new entrant, rather than a divestiture of one of the merging parties' business units, to maintain competition. Under the current D&O, if the proposed licensee fails to develop a DES product that can maintain competition, it can still retain the DES patent license. Even if the licensee chooses to retain the license while it attempts to develop another DES product, physicians and patients will not have a third alternative to J&J and Boston Scientific in the interim. To prevent this potential competitive harm, the proposed measures grant the Commission the power to transfer the license to another entrant who could step into the shoes of Abbott, should it fail to bring a DES product to market within the time frame that Guidant would have.

The Commission has employed similar measures in a number of its previous orders. In *Rohm and Haas Co.*, Docket No. C-3883 (issued July 13, 1999), the Commission required divestiture of certain intellectual property and other assets. The goal of the order was to provide the acquirer with sufficient assets to enable it to sell the divested product and obtain the capability to manufacture the product commercially. The order included provisions for periodic progress reports from the acquirer and the appointment of an Interim Trustee to "ensure that the Respondent and the Acquirer expeditiously perform their respective responsibilities" under the order and the Divestiture Agreement. If the acquirer ceased to sell the divested product or abandoned its efforts with respect to the divested assets, the order provided that the assets to be divested would revert to the respondent for re-divestiture.

The Commission included similar provisions in its the order in *Medtronic, Inc.*, Docket No. C-3879 (issued June 3, 1999), involving blood pump devices. The order required the acquirer of the assets to be divested to file periodic reports with the Commission and the Interim Trustee (if one was appointed by the Commission) and to submit a certificate of good intent to obtain FDA approval. The Commission was permitted to terminate the Divestiture Agreement if the acquirer failed to achieve certain milestones, e.g., if it failed to pursue good faith efforts or failed "to obtain all necessary FDA approvals" within one year from the date the divestiture was approved. If the Divestiture Agreement was terminated, the assets were to revert to the respondent for re-divestiture under the order. The initial acquirer under the order was Baxter Healthcare Corporation.

Similarly, in *SNIA S.p.A.*, Docket No. C-3889, 128 F.T.C. 168 (July 28, 1999), the order provided for an Interim Monitor to monitor the acquirer's efforts to obtain FDA approval to sell heart-lung machines and to develop its own manufacturing capability for those machines within a reasonable timeframe. The Commission's order also provided that if the acquirer failed to obtain the necessary approval and capabilities within two years after the divestiture agreement, the Commission could terminate the divestiture agreement and require divestiture to another acquirer. The acquirer in the *SNIA* case was Baxter Healthcare which, like Abbott, was a leading healthcare company but did not then manufacture or sell the products at issue. Similar provisions are included in the orders in *Roche Holding Co.*, Docket No. C-3809 (issued May 22, 1998), and *American Home Products Corp.*, Docket No. C-3740 (issued May 16, 1997). See also *Novartis AG*, Docket No. C-4150 (issued September 21, 2005); *Glaxo Wellcome plc and SmithKline Beecham plc*, Docket No. C-3990 (issued January 26, 2001) (proposed acquirers under the order included Novartis and Abbott Labs); *Ciba Geigy Ltd.*, Docket No. C-3725 (issued March 24, 1997).

The facts and circumstances of these cases are clearly analogous to the facts before the Commission here. Inexplicably, no comparable safeguards for competition in the DES market are contained in the proposed Johnson & Johnson order. If Abbott fails to commercialize a product or abandons development of DES, there is no apparent remedy under the proposed order now on the public record. The modifications suggested below are consistent with Commission precedent and are designed to help protect competition in the DES market.

#### **Monitor Trustee**

The licensee must be likely to enter in a timely fashion that will be sufficient to maintain competition. To that end, the Commission should modify the proposed D&O to appoint a Monitor Trustee to oversee Abbott's use of the J&J DES patent license and associated know-how in the development of its DES. Consistent with other orders of the Commission, the Monitor Trustee would track the acquirer's progress and report to the Commission about any problems (e.g., regulatory, clinical, operational, or commercial) that may prevent the acquirer from bringing a competitive DES product to market within the two-year time frame contemplated by the proposed Consent Agreement. (See Analysis at 3 ("the second half of 2007, approximately

the same time as Guidant's anticipated date of entry"). The Monitor Trustee should also have access to all records and facilities that relate to the research, development, manufacture, and sale of Abbott's DES product as well as the authority to interview employees about that process.

If the Monitor Trustee concludes by June 1, 2007, on the basis of objective criteria, that Abbott will likely not enter the DES market in 2007, then the Monitor Trustee would so notify the Commission. The Monitor Trustee would take into account Abbott's progress in conducting clinical trials, obtaining regulatory approval, ramping up volume manufacturing, and creating marketing and sales support for its DES products. For example, if the current Abbott DES clinical trials, ZoMaxx I and ZoMaxx II, were suspended for cause, then Abbott would likely not enter the DES market in 2007. Similarly, if Abbott failed to make timely regulatory filings with the FDA such that it could not obtain Pre-Market Approval in 2007, then Abbott would likely not enter the DES market in 2007. This way, the Monitor Trustee can track Abbott's progress toward bringing its DES product to market within the prescribed time period and report to the Commission if Abbott cannot do so for any reason.

#### **Divestiture Trustee**

The Commission should further modify its proposed D&O so if it appears that Abbott is not likely to enter the DES market with a DES in 2007, then the Commission will have the ability to terminate the DES patent license agreement and require its divestiture to another company that would be able to replicate Guidant in launching a DES product on a RX delivery system by the end of 2007. Because time is of the essence, we suggest that the Commission approve an alternative acquirer of the license by mid-August 2007. This date would allow the new licensee sufficient time to produce and begin marketing the RX stent technology in conjunction with its DES product to still enter the market during 2007, "approximately the same time as Guidant's anticipated date of entry." (See Analysis at 3.)

The Commission has frequently employed Divestiture Trustees to divest assets in cases where respondents have failed to do so. See *Frequently Asked Questions about Merger Consent Order Provisions*, <http://www.ftc.gov/bc.mergerfaq.htm>. Here, a failure by Abbott to enter, despite its best intentions to the contrary, would effectively mean no remedy at all in the DES market for the allegedly anticompetitive transaction. Such an outcome would preserve the present duopoly of J&J and Boston Scientific, but with the threat of Guidant's entry removed. Given the sensitive market involved and the Commission's conclusion that J&J's acquisition of Guidant *will* eliminate potential competition (Compl. ¶ 21.a.) (emphasis added), it is entirely appropriate for the Commission to appoint a Divestiture Trustee.

#### **Publicly Available Materials Fail To Justify the Proposed Order**

In the Analysis, the Commission states that the license intended to remedy anticompetitive effects in the DES market is transferable, "so that if Abbott's DES program is not successful, it will have the incentive and ability to transfer the RX license to another firm developing a DES,

ensuring that a successful third DES firm is able to enter the market with an RX delivery system in the relevant timeframe [i.e., in 2007]." (Analysis at 4.) However, the Commission does not offer an explanation of the "incentive" a licensee would have to transfer the license if it is unsuccessful, and the essential terms of the remedy that would explain the incentive have been redacted from the public record. Moreover, the redaction makes it impossible to assess the rationale for the Commission's decision and equally impossible to provide fully informed comment on the proposed remedy.

We have drafted these comments based on the available information. Earlier, we sought access to additional explanatory information under the Freedom of Information Act, but that request was denied. *See* Letter of November 17, 2005, from Joan E. Fina to Mary L. Azcuenaga (attached as Appendix 2).

Historically, materials relating to remedial divestitures under orders of the Commission have been required to be made public, subject to a showing of need for confidential treatment under the FTC Act. *See* Section 2.41(f) of the Commission's Rules of Practice ("All applications for approval of proposed divestitures . . . subject to Commission review under outstanding orders, together with supporting materials, will be placed on the public record . . ."). Cloaking materials relating to a proposed divestiture as confidential under the Hart-Scott-Rodino Act or as investigational materials thwarts the ability of the public to evaluate the proposed remedy and enables the Commission to avoid its obligation under the law to articulate a satisfactory explanation for its action, including a rational connection between the facts alleged and the remedial choices made. *See Louisiana-Pacific Corporation v. FTC*, 754 F.2d 1445 (9th Cir. 1985) (holding FTC's failure to articulate rationale arbitrary and capricious under 5 U.S.C. § 706).

In a letter filed earlier in the comment period, we sought through the comment process to obtain access to information that would enable us to provide more informed comment on the proposed order. *See* Letter of November 14, 2005 from Mary L. Azcuenaga to Federal Trade Commission (attached as Appendix 3). If the Commission does not make the modifications in the order that we have respectfully suggested, we continue to request that the Commission place on the public record the license with Abbott and any materials that show how Abbott's success or lack thereof will be determined, by whom the determination will be made and when, and any other material that bears on Abbott's incentive to license the relevant technology to another firm. We further request that the Commission extend the comment period to and including 30 days following the placement of these materials on the public record.

### **Conclusion**

Medtronic's proposed modifications to the Commission's D&O, respectfully suggested above, will ensure that the Commission accomplishes its goal of maintaining competition in this critical healthcare market. These proposed modifications also track provisions the Commission has employed previously in the medical device industry.

The measures proposed will provide the Commission with information about the progress of Abbott's DES program and permit another competitor to fulfill the intent of the Commission's approved remedy, should Abbott prove unable for whatever reason to bring a DES product to market in 2007. In addition, the recommended modifications would allow the Commission to transfer the DES patent license to another entrant with minimal delay and attendant harm to competition. The suggested modifications will provide physicians and consumers with a safety net should Abbott's DES product not enter the market in 2007; the Commission can assure them that they will have a third strong alternative to maintain competition no matter what.

Respectfully submitted,



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Enclosures

cc: Commissioner Thomas B. Leary  
Commissioner Jon Leibowitz  
Michael S. Wroblewski, Attorney Advisor  
Seth C. Silber, Attorney Advisor

# PRELIMINARY TRANSCRIPT

**Thomson StreetEvents<sup>SM</sup>**

**ABT - Q3 2005 Abbott Laboratories Earnings Conference Call**

Event Date/Time: Oct. 19. 2005 / 10:00AM ET

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## CORPORATE PARTICIPANTS

**John Thomas**

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**Thomas Freyman**

*Abbott Laboratories - EVP of Finance, CFO*

**Jeffrey Leiden**

*Abbott Laboratories - President and COO, Pharmaceutical Products Group*

**Richard Gonzalez**

*Abbott Laboratories - President, COO Medical Products Group*

## PRESENTATION

**Operator**

Good morning and thank you for standing by. Welcome to Abbott's third quarter 2005 earnings conference call.

[OPERATOR INSTRUCTIONS]

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I would now like to introduce Mr. John Thomas, Divisional Vice President, Investor Relations. Thank you, sir. You may begin.

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**John Thomas - Abbott Laboratories - IR**

Good morning and thank you for joining us.

Also on today's call will be Tom Freyman, our Executive Vice President of Finance and Chief Financial Officer, as well as Jeff Leiden, President and Chief Operating Officer, Pharmaceutical Products Group, and Rick Gonzalez, President and Chief Operating Officer, Medical Products Group. Tom will review the third quarter financial results and Jeff and Rick will cover the operating highlights in the Pharmaceutical Products Group and Medical Products Group respectively.

Following our comments, we will take any questions you may have.

Some statements made today will be forward-looking for purposes of the Private Securities Litigation Reform Act of 1995. We caution that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Exhibit 99.1 of our quarterly report for the period ended June 30th, 2005 on Securities and Exchange Commission form 10-Q and are incorporated by reference. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments.

In today's conference call, as in the past, non-GAAP financial measures will be used to help investors understand Abbott's ongoing business performance. These include such things as earnings per share, gross margin, SG&A, and R&D, each excluding specified items. In accordance with the SEC's Regulation G, and in line with Abbott's standard reporting practice, these non-GAAP financial measures are reconciled with the comparable GAAP financial measure in our earnings news release in Q&A, issued this morning and available on our website.

With that, let me turn over the call to Tom. Tom?

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**Thomas Freyman** - *Abbott Laboratories - EVP of Finance, CFO*

Thanks, John. And good morning, everyone.

For the third quarter, we reported ongoing diluted earnings per share of \$0.58, within our previous guidance range of \$0.56 to \$0.58. This performance included continued double-digit sales growth in both medical and pharmaceutical products, strong double-digit increases in both R&D and SG&A investments, and an improved gross margin ratio from the second quarter.

Before I discuss the various aspects of the P&L, I wanted to highlight our announcement today that we intend to repatriate a total of \$4.3 billion foreign earnings in accordance with the American Jobs Creation Act of 2004. This represents an additional \$3.7 billion beyond the \$600 million announced in the first quarter.

Turning to the P&L. Strong sales growth of 15% in the quarter was driven by balanced growth across our diverse product portfolio, led by Humira, Tricor, Kaletra, Omnicef, Abbott Diabetes Care and Ross, which included \$70 million of incremental revenue from our recently revised agreement with the U.S. promotion of Synagis. This revenue supported 18% growth in combined R&D and SG&A investment within the Medical Products Group, particularly in our Vascular Device and Diabetes Care businesses, as well as strong spending increases across the Company. Even excluding this additional investment, R&D and SG&A spending increased double digits.

Exchange favorably impacted sales by 1.1%. Gross margin ratio this quarter of 53.4% improved sequentially from the second quarter. Excluding the impact of Mobic and other Boehringer-Ingelheim or BI products, the ratio was 58.7%, up from -- up from 58.1% in the second quarter of 2005, also excluding BI products. Strong sales performance of low-margin Mobic and its transition from co-promotion to a lower margin sales distribution arrangement in June 2005 again caused a distorted ratio comparison for the prior year.

As discussed last quarter, we have identified a number of areas across the Company where we can reduce cost and improve gross margin. As part of this program, we continued actions this quarter to streamline our global manufacturing operations and we amended our co-promotion and distribution agreement with BI, as previously disclosed. As a result of the BI amendment, the gross margin ratio next year will be approximately 500 basis points higher than the ratio we would have expected if we continued to operate under the original agreement. As previously indicated, although we will not be recording sales for these products starting in 2006, the amount of pre-tax income Abbott earns from 2006 to 2008 under the amended agreement will be the same as the amount expected under the original agreement.

With regard to investment spending, combined SG&A and R&D investment this quarter increased nearly \$225 million. R&D increased nearly 15%, reflecting investment in our late-stage pharmaceutical pipeline, as well as incremental spending on clinical trials and our Vascular Devices business including drug-coated stents and carotid stents.

SG&A expense this quarter also increased nearly 15% driven by continued spending on new and ongoing promotional initiatives, particularly commercial activities related to sales force expansion and product launches, which is our carotid stent and new Humira indications for psoriatic arthritis and early RA, which Jeff will cover in his remarks.

Income from the TAP joint venture this quarter was \$116 million, in line with previous forecasts. Our forecasts of income from the TAP joint venture of \$425 million to \$450 million for the full-year 2005 remains unchanged.

Tax rate this quarter was 24%, also in line with previous forecasts.

For the first time, we are providing ongoing earnings per share guidance of \$0.75 to \$0.77 for the fourth quarter 2005. This reflects forecasted sales growth in the high-single to low-double digits with no significant exchange effect. R&D and SG&A

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increases in the mid-single digit range and the gross margin ratio approximately at the third quarter level, including the impact of BI products.

As a result of our fourth quarter guidance, we have narrowed earnings per share guidance for the full year 2005 to \$2.49 to \$2.51. This would reflect full-year performance in line with our original expectations providing -- provided at the beginning of the year, with double-digit sales growth and strong increases in investment spending.

In summary, we reported strong -- strong performance across many of our broad-based businesses this quarter. We also saw a high level of new-product activity at both Abbott and our TAP joint venture, which is why we're pleased to have Jeff and Rick on today's call.

With that, let's turn to the business operating highlights beginning with the Pharmaceutical Products Group. Jeff?

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**Jeffrey Leiden** - *Abbott Laboratories - President and COO, Pharmaceutical Products Group*

Thank you, Tom, and good morning.

For the first nine months of this year, as Tom mentioned, we've seen strong double-digit growth across our global pharmaceutical business. U.S. pharma up 14% and international pharma up more than 15% in the third quarter. This was the result of outstanding execution by our commercial teams in both PPD and AI. We've also made very good progress this year across our late-stage pipeline, including the recent FDA approval and launch of Humira for psoriatic arthritis and early RA, the FDA approval and launch of Zemplar capsules for secondary hyperparathyroidism, the FDA approval and launch of Kaletra Once-Daily and the FDA approvable letter for TAP's febuxostat for gout, as well as TAP's advancement of two next-generation PPI compounds into late-stage development. In addition we expect FDA approval of Kaletra tablets this quarter.

All told, we are on track to launch numerous new products or new indications over the next several years. And although we've had a few disappointments this quarter which I'll cover, our pharmaceutical business continues to perform at the high end of our industry.

Let me start with the highlights of our third quarter performance in the Pharmaceutical Products Group and then I will provide an overview of our late-stage pipeline. Our global pharma business delivered another quarter of strong double-digit growth which was driven in part by the continued success of Humira, which grew more than 50% this quarter, and remains on track to meet our 2005 global sales forecasts of greater than \$1.3 billion. Our prescription share in the U.S. is steadily increased with share in the RA market now exceeding 30%. At the end of last week, Humira surpassed the \$1 billion annual sales mark, with more than 115,000 patients worldwide now benefiting from the drug.

We also received both European and U.S. regulatory approval in the quarter for the early RA and psoriatic arthritis indications. These approvals actually came slightly ahead of our expectations, allowing us to launch these two important new indications well before year-end. The approval of Humira in early RA will offer patients another important option early in the course of their disease. Our data demonstrate that when treated early, one in two Humira patients achieve and sustain clinical remission. In addition, the Humira label now includes an indication to induce a major clinical response. This demonstrates Humira's effectiveness in controlling RA symptoms over a sustained period of time.

The approval of psoriatic arthritis brings us the first of six new disease state indications beyond RA, that we will launch over the next few years. In diseases that affect the skin, we have best-in-class superior efficacy data, two to seven times better than competitive self-injectable therapies. Psoriatic arthritis indication allows us to expand into the rapidly growing dermatology market. We are well-prepared for launch through the incremental build out and training of our Humira sales force and we estimate the psoriatic arthritis indication alone represents a \$300 million to \$500 million peak year sales opportunity.

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Earlier this month, we also submitted European and U.S. regulatory filings for ankylosing spondylitis, a chronic inflammatory disease of the spine. Approval of this indication next year would mark the third new indication for Humira. This indication also represents a \$300 million to \$500 million peak year sales opportunity.

Moving on to Tricor, which continues to perform well. Sales were 225 million in the quarter, we anticipate strong double-digit sales growth for Tricor in the fourth quarter, on track to achieve more than 20% sales growth for the full year. As you know, data from the Tricor field study will be presented at the American Heart Association meeting next month. Field is one of the largest studies ever undertaken in the diabetic population. The five-year, 10,000 patient outcomes trial, studying the benefits of Tricor and the primary and secondary prevention of heart disease in patients with Type II Diabetes. Currently, Tricor is used in only 15% of the diabetic patient population. So positive results from field could be important to expanding Tricor's use.

Let me turn to Kaletra which also performed well this quarter. We anticipate FDA approval of Kaletra tablets in the fourth quarter. Kaletra tablets allow patients to take fewer pills per dose and they won't require refrigeration, adding further convenience for patients. In November, we look forward to presenting new Kaletra biosuppression efficacy data, which we now have out to 7 years. This data demonstrates Kaletra's unique role in suppressing the HIV virus to virtually undetectable levels in patients new to therapy. Longer term, we continue to evaluate Kaletra's role as a mono-therapy treatment.

Synthroid continues to exceed our expectations; sales topped 350 million in the U.S. in the first nine months, and are on track to surpass our full-year guidance of more than \$400 million. More than one year after generics entered the market, Synthroid brand retention remains at approximately 60%.

With regard to Biaxin XL, in September preliminary injunction hearings took place against both Ranbaxy and Andrx and the judge's ruling is expected shortly. As you know, the same court granted Abbott a preliminary injunction against Teva this summer. This PI prevents Teva from launching its proposed generic product until a verdict is reached in the patent infringement trial which is not likely to begin until some time in 2006.

U.S. Biaxin sales performance in the quarter reflected the May launch of generics to Biaxin IR, while Biaxin sales outside the U.S. performed ahead of our expectations. Global Biaxin sales year-to-date of about 785 million are on track for our full-year sales guidance of close to a billion.

Omnicef had another outstanding quarter with sales growth of more than 70%. This is its 17th consecutive quarter of double-digit growth. We continue to expect strong double-digit growth for Omnicef for the fourth quarter and for the full-year.

In our renal business, Zemplar IV was up nearly 20% this quarter. We are still early in the launch of Zemplar capsules, our oral form of the product, but so far this year, we have been somewhat disappointed with our results. We've always contemplated a longer term adoption curve for the uptake of Zemplar capsules because it requires educating physicians about this disease, its consequences and its treatment. That said, we've taken a number of actions to improve our early launch performance, including better targeting our approach to key physicians and patients, and making kidney function and PTH testing more accessible for those patients. We are also encouraged by a prevalent study that will be presented next month at the American Society of Nephrology meeting that shows that the prevalence of hyperparathyroidism in stage III and IV patients is significantly higher than what we previously estimated.

In our anesthesia businesses, we announced last month the U.S. District Court ruled that Baxter did not infringe one of our Sevoflurane patents, though our patent was found to be valid. We filed an expedited appeal of this verdict with the U.S. District Court of appeals. We've also have a separate ongoing lawsuit against Baxter regarding two other patents. As a result of the previous court ruling, Baxter is prohibited from entering the market until after December 10th of this year. We will continue to promote Sevoflurane, known as Ultane in the U.S., and we intend to ingress – to aggressively compete to maintain our market-leading share. As we previously stated, this ruling will have no meaningful impact in 2005; however, if Baxter would launch at risk, it would have an impact on Sevoflurane sales and market share in 2006.

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So looking ahead to the fourth quarter, we expect low double-digit growth in our U.S. pharmaceuticals business and high single-digit growth in our Abbott international business.

Let me move on to TAP, our joint -- to the TAP joint venture, whereas Tom stated, our forecast of full-year net income of 425 to 450 million remains unchanged. TAP expects a particularly strong fourth quarter due to favorable year-over-year comparisons. There's been quite a bit of activity in TAP's pipeline this quarter, so I want to also review these key developments.

TAP has received an approvable letter from the FDA for febuxostat for management of hyperuricemia in patients with gout. TAP expects to address the contents of the letter and to obtain final approval for febuxostat in a timely manner. New drug application for febuxostat was submitted in December 2004, and was based on a number of studies including the largest Phase III studies of chronic out patients in the United States to date. Capital presented second Phase III pivotal trials for febuxostat at the American College for Rheumatology meetings this fall. As you will remember, febuxostat is an oral once-a-day therapy, and the first new drug to be developed in 40 years in the U.S. for gout. This approvable letter has no impact on Abbott's previously stated guidance for 2005.

TAP also recently initiated Phase III clinical studies for TAK-390 MR, a new modified release PPI, for the treatment of acid-related disorders. TAP anticipates submitting for FDA approval by early 2008.

TAP also signed a licensing agreement with Ilyang Pharmaceuticals for ilaprazole, a new PPI compound that will enter Phase II studies early next year.

Finally TAP and its licensing partner, Schering AG, announced last week the amendment of Asoprisnil extension studies, which patients were able to enter following the Phase III control trials. TAP will be finalizing submission plans with the -- with the FDA for Asoprisnil in the coming months and hopes to file an NDA in the U.S. in 2006.

I'd like to spend a few minutes on Abbott's pipeline. As I mentioned at the beginning of my remarks, we've made tremendous progress this year executing on many of our late stage opportunities. And we've made great strides over the last six years in restocking what was quite frankly a fairly weak pipeline in the late 1990s. Through acquisitions like [canol] and our own internal R&D efforts, we've created a large basket of commercial opportunities. And that's how we view our pipeline in both pharmaceuticals and medical products; we have a basket of promising compounds and medical technologies. Not all of them have the same risk-reward profile and not all of them are going to succeed. That's the nature of pharmaceutical development and in many ways the paradox; without risk there's no innovation, without innovation there's no reward. And we'd all like reward without risk. That said, we expect that most of our R&D projects will succeed and that's certainly what we've seen in the last few years. Xinlay is a good example of this paradox between scientific innovation and risk.

Xinlay represents pioneering science in a treatment area where there's been no real innovation since chemical castration 40 years ago. As you know, it's an oral once-daily compound in a class of drugs that's never before been developed for prostate cancer until Abbott. We're very proud of the work that's been done by our scientists to develop a novel treatment like Xinlay and the drug still holds great promise for the thousands of men who suffer from this horrible and excruciating painful disease. Clearly, we are disappointed that we received a non-approvable letter from FDA last week which followed a similar recommendation by an advisory panel in September. What we heard at that ODAC advisory panel was that we needed a statistically significant trial result in an intent to treatment patient population. We were encouraged by the ODAC comments that Xinlay did indeed have activity and that new treatments are needed for prostate cancer. I want to emphasize that this non-approvable decision pertains to our filing in the metastatic patient population, and does not affect our second Phase III trial known as 244, in the non-metastatic population. We anticipated results from the 244 trial in the first half of 2006, and at that time we will be able to update you on our regulatory plans for Xinlay.

Simdax is in Phase III development for congestive heart failure and there are two data presentations coming up at the American Heart Association meeting in November. There is also a pivotal Phase III trial REVIVE II will assess the impact of Simdax on the signs and symptoms of congestive heart failure. You will remember that REVIVE II is our pivotal trial for U.S. approval. Our second

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trial, SURVIVE, was conducted in Europe and examines the effects of Simdax versus dobutamine on mortality in patients with acutely decompensated heart failure.

In addition to the recent filings of Humira for ankylosing spondylitis, we remain on track with our clinical trial plans for Humira's other indications, most significantly Crohn's disease and psoriasis. I am also pleased to announce today that we've made decision to initiate Humira studies for the treatment of ulcerative colitis. So, in total, Humira will have six distinct indications including psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, juvenile rheumatoid arthritis and now ulcerative colitis. With these low-risk pipeline opportunities, several with better than \$500 million peak year sales potential, Humira is well on its way to reaching multi-billion dollar sales potential.

Let me briefly touch on ABTA 74 our anti-IL biologic in Phase II development for multiple sclerosis, psoriasis, and Crohn's disease. We're encouraged by early data for this class of molecules in both psoriasis and Crohn's disease and we've just completed enrollment of our Phase II multiple sclerosis study. In addition, we are very confident in our intellectual property position around this compound. Vicodin CR, our treatment for pain is also progressing to Phase III, which we anticipate will begin by year-end or early next year.

Tricor is another significant opportunity in our pipeline. In addition to next generation Tricor products, we continue to work on a fixed-dose combination product that could represent a market-changing cholesterol treatment. There's no other product on the market or in development that will be able to effect all three lipid parameters, HDL, LDL and triglycerides. With only 3% of statins used in combination with Tricor, this remains a large untapped market opportunity. This combination product could make Tricor a multi-billion dollar franchise within the next five years.

With that, let me turn the call over to Rick for a review of the Medical Products Group and then, of course, we'll be glad to take your questions. Rick?

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**Richard Gonzalez** - *Abbott Laboratories - President, COO Medical Products Group*

Thank you, Jeff and good morning, everyone.

Earlier this year we talked about the progress we are making in reshaping the Medical Products portfolio and how we're focused on three key objectives. This morning, I'd like to briefly review the progress we are making against those objectives, particularly in the backdrop of the third quarter performance and our recent new product activities.

Our first objective is to build a stronger mix of innovation driven high margin businesses that compete in large and fast-growing markets. We've accomplished a great deal towards this goal, primarily by building and adding new businesses, such as Abbott Vascular Devices, Abbott Diabetes Care and Abbott Spine.

Our second objective has been to drive significant improvement in the financial performance of our medical products business. Today's third quarter results marked the sixth quarter in a row that we've reported double-digit or high single-digit growth for the Medical Products Group, a significant improvement over our historical performance levels.

Our third objective has been to continue to advance a strong new product pipeline that would compliment our pharmaceutical business. Towards the end of my remarks, I'll discuss how we've executed against our new product strategy with some key launches that began in the third quarter and here early in the fourth quarter and we expect to continue through 2009.

With that, let me start with a brief review of our third quarter performance in medical products. In our worldwide diagnostics business, sales were up 9% including strong performance from Abbott Diabetes Care, where Abbott continues to gain market share with its FreeStyle and MediSense glucose monitoring products, as well as our point of care diagnostic and molecular diagnostics businesses. In Abbott's core diagnostics business which includes, as you know, immunoassay, clinical chemistry

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and hematology, global sales were up modestly driven by international growth of 5%, partially offset by U.S. sales declines in the quarter.

ADD accomplished a number of important milestones in third quarter including the U.S. launch of the CELL-DYN Sapphire, an automated high volume hematology instrument. The Sapphire has been available ex-U.S. since May and customer feedback has been very positive and placements are exceeding our expectations. ADD remains on track to surpass its goal of 1500 architect placements this year; in fact, in the first nine months of 2005, ADD placed more than 1200 architect systems worldwide.

Turning to the fourth quarter, just last week we announced the long-awaited introduction of Abbott PRISM to blood banks across the United States. The PRISM instrument is the first fully automated blood-screening analyzer and is used outside the U.S. in more than 30 countries. Nearly half of these countries currently rely on PRISM, to screen 100% of their blood donations. U.S. launch follows the FDA approval of Hepatitis B core, with additional blood bank assay approvals expected over the course of 2006.

In the fourth quarter, we expect ADD to grow in the low to mid-single digit range, with improving sales growth in the U.S., driven in part by PRISM. In Abbott Diabetes Care, we continue to see just outstanding performance as sales grew nearly 30%. Business has sustained momentum on the strength of both the Precision and FreeStyle brands. And new product launches combined with strong execution have led to continued global market-share gains.

In the third quarter, Abbott launched a FreeStyle Connect, a hand-held point of care blood glucose testing system for the hospital market. Looking ahead to the fourth quarter, we expect Abbott Diabetes Care to again deliver strong double-digit performance and for the first time in its history, surpassed the billion dollar sales mark. In molecular diagnostics, sales grew more than 30%. During the quarter Abbott and Solera diagnostics launched in Europe a real-time PCR test for monitoring hepatitis C viral load in patients. This test allows physicians to better monitor and treat HCV; the launch expands the infectious disease menu on Abbott's automated M2000 system which also includes an assay for HIV viral load. Moving forward, Abbott plans to expand its assay offerings on the M2000 and secure a competitive hold in this billion dollar infectious disease market.

In the fourth quarter, we expect strong double-digit growth again from our molecular diagnostics business.

Now, turning to our point of care business. Sales grew nearly 20% in the quarter. And we expect this type of growth to continue following three key new product launches, which I'll touch upon here in a moment. In the fourth quarter, we expect point of care to deliver more than 20% sales growth. So overall, looking forward to the fourth quarter, in our worldwide diagnostics businesses, we expect continued double-digit sales growth, led by strength in diabetes care, molecular and point of care, and by improving trends in our core immunochemistry business, particularly here in the United States.

In our nutritional business, worldwide nutritional grew 20%. Sales this quarter in the U.S. business were up more than 20%, driven in part, as Tom mentioned, by a revised agreement with Medimmune for the U.S. promotion of Synagis as well as strong performance in our adult nutritional segment. This was partially offset by flat sales year-over-year in our pediatric nutritional business. Internationally, our nutritional business continued its strong momentum. Most significantly, across Asian markets, including China. Looking ahead to the fourth quarter we expect our international nutritional business to deliver high single-digit growth. For Ross, we anticipate low single-digit growth impacted by the declining consumption in the low-carb healthy living segment.

In Abbott Spine, sales grew more than 45% driven by continued success of PathFinder and our growing international presence. In the fourth quarter we again anticipate strong double-digit growth.

This quarter in Abbott Vascular Devices, we received FDA approval and launched our exact stent and immunoshield filter for carotid stenting in higher risk patients, making Abbott only the second company to enter this market in the U.S. Early performance of the product looks very strong. We've received encouraging feedback from physicians regarding the ease of use and effectiveness of our carotid platform. We expect to gain significant share in this market over the next six months. ACT 1, as you know, our

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groundbreaking carotid clinical trial in asymptomatic patients that we initiated earlier this year; enrollment is steadily increasing as we continue to expand and train additional sites. An asymptomatic indication which significantly expand the market opportunity, for carotid stenting over time.

Looking at the fourth quarter with the launch of StarClose here in the U.S. and our carotid platform we expect double digit growth from Abbott Vascular Devices. Now I'd like to review some of the emerging opportunities out of our MPG pipeline. Let me start with an update of our DES program including our clinical trials on ZoMaxx, and our next-generation DES products. ZoMaxx I, our ex-U.S. clinical trial, completed enrollment in July; as a reminder, ZoMaxx I is a 400 patient trial comparing ZoMaxx to TraXis with a nine month in segment late loss end point. We expect to present data from ZoMaxx I next year and we remain on track for a CE Mark in the second half of 2006. ZoMaxx II is our U.S.-based clinical trial again comparing ZoMaxx to TraXis, with a nine-month clinical end point of TBR. We're on track with enrollment thus far with over 100 patients which is consistent with our timeline, to complete the total study enrollment of 1670 patients by next summer. We anticipate a U.S. launch of ZoMaxx in early 2008.

We also have a next-generation DES program behind ZoMaxx. A TCT this Friday, we are presenting preclinical data from this program, which combines [zotorolamis] and dexamethasone on our i-STAT platform. Our goal is to target the difficult to treat patient population such as diabetics where restenosis remains high. We believe that [zotorolamis] and dexamethasone are uniquely suited to improve clinical outcomes in this patient population. And we are very encouraged with the preclinical results that you'll see.

In our vessel closure business we expect to launch StarClose here in the U.S. in the coming weeks. StarClose is our clip-based vessel closure device. It gives physicians a fast and secure close in less than 30 seconds. Outside the U.S. StarClose has been used in more than 50,000 patients. And continues to perform well where our share is increased by more than 50%. At TCT we presented data that demonstrates StarClose is effective and safe. We anticipate an FDA approval and launch of StarClose in the fourth quarter.

In Abbott Diabetes Care we anticipate launching our Navigator continuous blood glucose monitor in the second quarter of 2006. As a reminder, we are completing two additional clinical studies here to support our PMA filing for a reportable result claim.

In Abbott Molecular, we plan to begin launching real time PCR assays here in the U.S. in the first half of 2006.

In our point of care business, by the end of the year, Abbott plans to launch CK&B and B&P, two important cardiac markers that will join Troponin which is already available in the i-STAT platform. Additionally in point of care we are on track to launch the i-STAT Chem 8 panel by the end of the year which measures 8 key clinical chemistry tests from just a single cartridge. Our goal over time is to get this product away, allowing physician offices access to this important technology.

Finally in Abbott Spine we recently initiated a U.S. clinical study for the Wallace system; this is used for the treatment of mild to moderate degenerative disc disease. This innovative spinal implant technology is designed to stabilize the spine and reduce pain while preserving patients' range of motion. The Wallace system has been used in Europe to treat degenerative disc disease now for a number of years.

So in summary, we continue to make very good progress against those three key objectives. We have built a stronger mix of innovation driven businesses. We are continuing to drive significant improvement in business performance, and we're advancing a very strong pipeline of new products.

With that, I'll turn the call back over to John. John?

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**John Thomas** - *Abbott Laboratories - IR*

Thanks, Rick. And we're going to open the call up now to your questions. As we always ask as a matter of professional courtesy if you could please try to limit your questions to one topic. We would appreciate it. Thank you.

And operator, you can open up the call.

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## QUESTIONS AND ANSWERS

**Unidentified**

Thank you. [OPERATOR INSTRUCTIONS] our first question today is from Michael Weinstein and please state your company name.

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**Unidentified**

Hello. Hello?

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**Unidentified**

Hello.

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**Unidentified**

Can you hear me?

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**Unidentified**

Yep.

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**Unidentified**

Actually, this is Adam with ex calibre Research. A couple of questions regarding costs. Very recently how are you guys looking to reduce costs with your supply base by collaborating with them better to overall improve your supply chain efficiency?

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**Unidentified**

Well, we have pretty extensive programs with our suppliers, we have corporate coordinated across the operating units purchasing activities and we've had an ongoing program for many, many years that addresses efficiencies in the supply chain with those vendors. And we set targets every year and have delivered savings on those incrementally year in and year out to help us offset the inflationary impacts on the business.

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**Unidentified**

One thing I noticed over the last couple of years following your company's -- always been a key driver of your entire operation. How are you making sure your suppliers are meeting your quality standards? Are you score carding them on a regular basis, are you meeting with them to -- what are you doing to make sure they're meeting your strict guidelines?

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**Unidentified**

This is Rick Gonzales. We have a problem really across all of Abbott where we as part of our quality system approach where we have metrics by which we measure suppliers, we go out and do quality audits against those suppliers. So we do a number of things to ensure we manage not only raw materials but even OEM suppliers of products.

**Unidentified**

What are the specific raw materials that are concerning you going to next year?

**Unidentified**

You know, we don't have anything in particular on that to talk about. Nothing unusual that any other company wouldn't have to deal with. Can we take the next question, please.

**Unidentified**

Thank you. Our next question is from Rick Wise and please state your company name.

**Unidentified**

Good morning, everybody. Rick Wise, Bear Stearns. A couple questions. First, can you talk a little bit -- more about the impact -- potential impact of SAOEFL FLOR reason. You said if Baxter launches at risk my assumption is they will launch at risk. How do you fight back and what steps can you take if Baxter launches and maybe you can talk about the potential ramifications.

**Unidentified**

Yeah, Rick, this is Jeff. As we said, we don't see any ramifications this year as you know Baxter has presented from launching until December 10th of this year. With respect to next year, I think it's just too early for us to speculate. First of all we don't know what Baxter's going to do with respect to launch second we don't know how they're going to do it if they do launch. We obviously have a series of contingency plans already in place to deal with that both in the U.S. and ex-U.S. but I think until we see what they do and how they do it it's just impossible to give you an accurate prediction for 2006 and beyond it will have an impact but how much sim possible to say at this point.

**Unidentified**

Okay. Two other quick ones. One Jeff can you address Tricor. Tricor was weaker we looked for this quarter was that petition from Vi tore a, channel restocking or -- I mean why are you so optimistic for the fourth quarter can turn around and maybe a last one for Tom on the SG&A and R&D growth front. Going forward, ex -- ex-the Synagis impact, are -- or re -- re -- changes there. Are we going to see SG&A or R&D grow equal to or greater than the sales growth rate, any perspective would be welcome. Thanks.

**Unidentified**

Rick, this is Jeff. Let me answer your Tricor question first. We remain very enthroughtsiasic about Tricor for a number of reasons. The launch of the NFE went as well as or better than we expected and in particular as you probably have seen, we've maintained

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our very high market share there with the non-AB rated competitors really with less than 1% market share and I think that's a tremendous accomplishment by our commercial group. Secondly, we're following scripts most carefully obviously and if you look in the third quarter, script growth actually exceeded sales growth partly due to some small inventory changes but I think the script growth well greater than 20% growth for the year is what keeps us so encouraged. And finally I think the thing -- the other thing that did happen in the third quarter is there was some market flowing here. You probably have been watching this lipid market which has been growing historically at around 14.2% for the year. And that really slowed for the first time to high single--digits. We think that was a complicated mix of things. Some of our competitors actually did pull back on their SG&A spending in that category during the third quarter which slowed the market. Vi Toren actually has increased their promotional push quite dramatically during the third quarter so there was some change with respect to the promotional mix and the total promotion. Nevertheless, as you know Tricor does not compete directly against the stat.ens or vie toren. It still has a unique place in this market. We've maintained our essential -- essentially high market share in the script growth is very strong so take all those things together we remain very confident about Tricor's growth both this year and next year I might add.

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**Unidentified**

On the SG&A and R&D, I guess there's a few things to say. In general, we are trying to focus our incremental investment in the marketing and sales force areas that really can add to the momentum of the business and we try to manage very tightly the administration element of that line item so I think even if we were to grow that line item somewhat lower than sales we'd be focussing the incremental resources in areas that really count and creating some productivity and potential leverage in the admin areas. As I indicated in the fourth quarter we expect mid-single increases in these areas but even with that with our year-to-date strong investment performance, I think you'd see R&D increases in line with our previous forecasts earlier in the year in SG&A quite a bit above the forecasts we provided earlier in the year so we have been investing more this year and we'll try to give you a little more clarity on that when we provide 2006 guidance.

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**Unidentified**

Thanks, Tom.

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**Unidentified**

All right. Thanks, Rick.

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**Unidentified**

Thank you our next question is from Mike Weinstein. Please state your company name.

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**Unidentified**

J.P. Morgan. Can you hear me.

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**Unidentified**

Yeah, is this the real Mike Weinstein.

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**Unidentified**

Yeah, I think we've got an impostor. A couple questions and then I'll spread it between Jeff and Rick. Jeff, can you help us just as we go into HA and we get ready to see the revived -- survivors -- results. How we should think about those two trials with revive 2. What -- what -- in your view is a good outcome for that trial? Just -- maybe just lay out the end points and then with survive, just talk about using i-Bute mean as a control and how meaningful that is or not and address that -- that overall issue. Thanks.

**Unidentified**

Well, Mike as you know I can't say anything about the results because AHA has a very strict confidentiality policy prior to the results. What I can do is to answer your questions about trial design and ends points, etc. So you will remember that revive II is our pivotal trial in the U.S. We had -- or actually Orion before us had talked with FDA about what was required to get approval in the U.S. and it's come to an agreement that single additional trial looking at the ability of Leevo Samendon to improve signs and symptoms of patients with heart failure was needed in conjunction with FDA we designed a -- what I think is a very creative and very meaningful clinical end point at the primary end point of the study. And just to remind you of how the study was done. About 600 patient study. Patients with acutely decompensated heart failure would come into the hospital they would get treated with intraconvenientous diuretics and whatever else physicians wanted to treat them with for the first 12 to 24 hours if they failed that, they would then get added onto their regime either placebo. So not really a purely placebo controlled trial I would call it standard of care against standard of care plus LAOEVo -- and then we're following the clinical progress in six hours, uh, 24 hours, five days, and then we follow the patients all the way out beyond 30 and 180 days. So that's the way the trial is set up. Obviously a good result would be to hit our primary end point with statistical significance that's what regulators require that's how the trial was designed and you'll hear that answer I believe on Monday at American Heart Association.

**Unidentified**

COMBRAIT. Rick --

**Unidentified**

Would you like me to answer survive.

**Unidentified**

Yeah. I was hoping you were going to touch both but go ahead.

**Unidentified**

With respect to Survive, this was a trial that Orion negotiated with the European regulators. That's the European trial. And as you know in Europe, in the majority of cases the Europeans really want to see your drug tested against what they consider standard of care. And in Europe -- frankly as well as in the U.S. but in Europe VEL Bute mean is the standard of care and so the regulators wanted to see a trial comparing LAOEVo is a mendon against doe Bute mean. There -- the primary end point is mortality at 180 days, there are secondary end points of shorter term mortality as well as clinical improvements. And so we are just finishing analyzing that data now and again you'll see it at AHA I believe on Wednesday afternoon.

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**Unidentified**

Perfect. And the question for Rick is relative to ZoMaxx II and -- the question there you gave us a brief update on where you are on enrollment. How do you expedite that? It seems -- since that enrollment is going at this point at least relatively slowly. I know there's a second stage which you'll enter into which will allow you to increase the number of Septemberers but, you know, 100 plus patients and just comparison to what -- where guidance -- where -- their enrolment of their spirit 2 and three trials. It seems like so far it's been challenging and I know you're saying you'll have it done by next summer but kind of what gets things going?

**Unidentified**

Mike, it's actually a good question. If you look at the trial, I think one of the metrics we look at carefully is enrollment of patients per month per site. And if you look at that metric, we are tracking about what the industry standard would be, two to three patients per month. But, remember, initial approval from FDA was for ten sites, um, FDA has now agreed to allow us to expand to 15 sites in the U.S., and add 10 additional sites outside the U.S. And so we're ramping those sites in right now. And we'll go back to FDA shortly, uh, and talk about expanding it beyond the 15 sites in the U.S. And so it's really related almost directly to the number of sites that you can have on-line. Enrollment's pretty consistent across these trials and I'd say the two to four patients per month range. Societies are really the key. Second thing I'd tell you is there is a trade-off between speed and ensuring a very high-quality result out of the trial and we're trying to walk the balance where we ensure that we have very good compliance in the trials, and that the quality of the data at the end of the trial is of the highest quality possible because a month or two difference in launch day is not as significant as having a problem with the quality of the trial. So as we're taking the sites up we're being very careful to make sure we have trained them well, that we're monitoring well, etc. And so it is a balance.

**Unidentified**

Mike, did you get that -- are you clear on that two to four patients per month per site?

**Unidentified**

Yeah. Absolutely. I mean -- that you guys need more sites.

**Unidentified**

Correct.

**Unidentified**

Okay. Anything else?

**Unidentified**

That's great. Thanks.

**Unidentified**

Okay. Thank you.

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**Unidentified**

Thank you. Our next question is from Glen Novarro. And please state your company name.

**Unidentified**

Yes, bask of America securities. Two questions for Jeff. One on Tricor. Can you talk to us about the combination product. I've asked this question before, but I'll try again. If you can give us a sense of what drug you're going to combine it with. And most importantly, there's a Pfizer compound that will compete against a combination Tricor product and I believe that will come to the U.S. in 2007. So maybe can you give us the timeline for your combination product and will it come out before the Pfizer product? And then secondly on Simdax, the drug is going to go -- compete in the marketplace against Narcore, gnarl core is on decline. What do we need to see out of Revive II to make us believe that Simdax can come out, take significant share from natural core, calm physicians and be a significant drug? Thanks.

**Unidentified**

Well, thanks, Glenn. I must say you're consistent but I'm also consistent with respect to Tricor. We've told you before that we -- we are developing a combination product with the stat.en. We haven't disclosed to you which stat.en and I won't disclose which one today what I will say is that program is ontrack for -- for development. You will start to see some combination data. That meaning stat.en plus Tricor early next week. Because we have a couple of trials going on with two drug therapies. And what I would tell you about the compound is that its profile at least this combination product, should make it best in class with respect to the combination of all three lipid parameters, meaning triglycerides. Now, you asked about the Pfizer compound, combination compound, um, what we understand and again I certainly won't be -- speak for Pfizer what we understand is that that combination product is unlikely to launch before 2008. And our timeline with our combination product would also get us there in 0008 so we think that we would be competitive there. With respect to the profiles we've obviously only seen limited data from them and we have our own data but I would tell you that if one looks theoretically at what the profile should and so far do look like, the advantage of the TriCorr combination product is it would have more profound lowering effects on triglyceride than the Pfizer compound. And obviously we would be using two drugs that have had a lot of use in the marketplace -- safety is not in question and I think that's an advantage in our -- from a risk standpoint in our combination product development strategy. Does that answer your question about --

**Unidentified**

Just a follow-up before you go to Simdax. You know, we keep hearing in the marketplace that LDL and HDL are more important than triglycerides. Is there going to be a change in how we treat overall CLETS troll over the coming years that give you the confidence that the combination product and its benefit on triglyceride will have a major impact in the marketplace.

**Unidentified**

Yeah, very good question. One piece of data that's going to be directly relevant to that is the field trial which you'll hear about at the American Heart Association and I can't say anything about the results of that trial but I would tell you that it's the largest outcomes trial for a fine rate in diabetic patients ever done. And I think if we have positive results from that trial announced at AHA and it's an outcomes trial it LBT first piece of very strong data in a very large population of patients about the importance of triglyceride lowering. And remember that only -- less than 15% of diabetic patients are currently treated with any sort of triglyceride lowering agents so there is a very large commercial and clinical opportunity frankly in that patient population. So I think it's those kinds of data that will -- will drive the importance of triglycerides and we'll start to see that next month. Now, with respect to Simdax, again I'm not going to comment on natural core at all. I would just tell you that as you know, this is an area of huge medical need, heart failure. There is just really is -- not a lot out there that -- that can be used to treat these patients and when they come into the hospital with acutely decompensated failure they desperately need some sort of treatment. I

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think one of the things that we like about our trial design is that we're looking at multiple end points, starting at six hours and going all the way out to five and 30 days, as you know most of the Simdax -- most of the natural core data is very short term and in fact label is really based on a single three-hour time point. But I think one of the things that we need to look for in the AHA data is what are the outcomes across a series of time points which is how our trials are designed can we really show clinical benefits not just three hours or six hours but that goes out to multiple days gets patients out of the hospital, etc. and so you'll hear something about that I think at AHA.

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**Unidentified**

Okay.

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**Unidentified**

Okay. Thank you.

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**Unidentified**

All right. Thanks, Glenn.

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**Unidentified**

Thank you. Our next question is from Sarah Michelmore and please state your company name.

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**Unidentified**

Yeah, thanks. Sarah Michelmore, SG Cowen. Just to follow up on the Simdax. Jeff, could you remind us what the priority review entails for Simdax and would it be your intention just to file the revised Q2 data or would you -- survive II -- and the end POITS.

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**Unidentified**

I'm really not going to comment on a regulatory strategy or a -- strategy for two reasons. One, you know, we are showing the data and discussing the data with both FDA and the EMEA and we don't comment on our discussions with regulatory agencies and number two because of the confidentiality around AHA, I really don't feel comfortable talking about our regulatory strategy because I think that in a way is sort of revealing what the trials show and we're just not going to do that before AHA, they have very strict rules about that.

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**Unidentified**

Sorry, Sarah, is there something else you want to ask.

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**Unidentified**

A question for Rick on Navigator, probably another regulatory question but I guess you guys are still sticking to the Q2 '06 launch that you were talking about I'm surprised that you haven't submitted the data from the additional trials and I'm just wondering in terms of regulatory timing how that works so you actually supplementing your PMA? I'm just wondering if there's any risk for slippage on that timeline? Thanks.

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**Unidentified**

You know, if you actually look at the timeline it is a supplemented PMA two additional trials, as we've said in the past, the trials are going well, one of them takes a little bit longer to complete. But it is designed to be able to get this reportable result playing and so we're on track. We feel comfortable with that time frame.

**Unidentified**

And as a follow-up Rick I've heard from the field that you guys are actually hoping to get a five-day sensor claim as opposed to the original three day that was filed?

**Unidentified**

That is correct.

**Unidentified**

Okay. Thank you.

**Unidentified**

Thanks.

**Unidentified**

Thank you. Our next question is from Glen Risen and please state your company name.

**Unidentified**

Hi. It's Mat for Glen at Morgan Stanley. So a couple questions. First on -- on diagnostics. You talked about over 1200 architects placed so far? First nine months. Are you expecting given the fourth quarter capital cycle and kind of an uptick in fourth quarter or -- or a slowing? How do you expect the rest of the year to go?

**Unidentified**

Mat, we would expect it will actually surpass the 1500 as we talked about. And so it will track at or slightly above our rate going into the first nine months.

**Unidentified**

Okay. Looks like it came in a little bit in the third quarter. I don't know if I'm mistaken there. But I would -- was wondering if it'll bounce back in the fourth quarter.

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**Unidentified**

Remember, a significant number of these go into Europe and Europe basically shuts down in the month of August so you normally do get a little bit of a slump in the third quarter and a pretty heavy recovery in the fourth quarter.

**Unidentified**

Okay. Can you give us an idea of how many of these went into Europe or what the breakout was?

**Unidentified**

The breakout's about what our sales breakout is.

**Unidentified**

Okay. So maybe 75% Europe, something like that.

**Unidentified**

Yeah. I'd say two thirds into Europe, a third in the U.S.

**Unidentified**

Okay. And then also on diagnostics, you know, you have this automation platform coming maybe -- you know, first half of next year, is that right, the -- the new automation platform that you showed at the AACC?

**Unidentified**

We do plan on actually shipping units in the first half of next year, correct.

**Unidentified**

Okay. Now, does that preclude you from getting into cycle -- evaluation cycles ahead of that, or -- or where -- do you stand in terms of just being able to market that?

**Unidentified**

Well, we do have systems that are up and running that we use as demonstration sites as you probably know we had three very large closes that use this automation system. We'll be announcing some additional closes here in the no, sir too distant future that will be similar to those so sure we're actively selling the product, demonstrating the product.

**Unidentified**

Great. And then you talked about some expansion towards the end of this year beginning of next year, can you give us an idea where -- what new tests we should expect next and when?

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**Unidentified**

Okay. I think this is going to be the last one I'll be able to answer for you.

**Unidentified**

Okay.

**Unidentified**

Most significant opportunities for new tests will be here in the U.S., expanding menu around met bollics and hepatitis and our goal is to have all of those submitted by the end of this year.

**Unidentified**

All right. Mat, we need to take some more questions.

**Unidentified**

I'll let you go. Okay. Thanks.

**Unidentified**

Thank you.

**Unidentified**

Next question.

**Unidentified**

Thank you. Our next question is from Kathryn Martin elly. Please state your company name.

**Unidentified**

Thank you. With Merrill Lynch. One question first just how we should think about metaMAOUN and the milestone payments going forward, just to be clear the 70 million was all incremental in the quarter and how do we think about that over the next couple years?

**Unidentified**

Yes, Sarah. That's correct. On the 70 million. And the way this agreement was restructured is that we will -- based on additional activities for the product have higher commission rates going forward. So that the remainder of '05 and '06 we'll be earning more than we would have under the previous agreement. And bringing more definition to the -- to the end point of the

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agreement. I think it would be useful since we've got Rick here for him to just provide a minute of -- of kind of perspective about -- about the rationale for this deal.

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**Unidentified**

Sure. Thanks; if you look at this arrangement I tell you we had three strategic objectives when we looked at renegotiating the contract. One was to minimize risk to Abbott, two was to maximize the value to Abbott and three over time was to redeploy those resources to other products and businesses that we will have over the long term. Our partner meth tuh MAOUN made it very clear to us that upon the approval of new max that they wanted to market that product in the United States as you probably know we have the rights outside the United States. And so with that, we knew that we believed new max and still believe today has a very high probability of approval in the U.S. in the 2008 time frame that we will lose Synagis and so we decided to renegotiate the contract to minimize any financial risk to us of an early approval of new max, that wouldn't have been in our forecast, to give us the opportunity to maximize the value of the agreement to Abbott and the opportunity frankly to overachieve. If we -- if we sell more, if we promote more, we can actually overachieve the targets beyond the milestone payment. And then finally and probably most importantly was to take those resources and redeploy them to other products that -- long term will provide more value to Abbott products like ZoMaxx, carotids, diabetes, StarClose. We have a StarClose vessel closure sales force expansion that we're doing here in the U.S. and in Europe. And so we are using those resources to be able to expand and then redeploy the pediatric resources that we have back to our nutritional products over the long term. So -- and you saw some of that in the third quarter. You saw SG&A spending, medical products was up almost 20%, about -- a little over 18%. And that was additional clinical trial work and -- and ZoMaxx as well as expansion of sales forces for both vessel closure and carotids here in the U.S. and overseas. And so our goal was to maximize the long-term benefit here and frankly I think this has worked well for us. It's done exactly what we expected it to.

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**Unidentified**

Thanks, Rick. Anything else Kathryn.

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**Unidentified**

Well just -- so to be clear on the 70 million that's what we should be assuming on a quarterly basis through '06?

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**Unidentified**

No. That's -- I think that -- that's high. And we're really going forward it's going to be commissions based on sales as we roll forward.

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**Unidentified**

So there's no other major milestone payment.

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**Unidentified**

No SNAOSHGS no. And we'll explain it to you every quarter as necessary.

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**Unidentified**

And then just one last question more of a clarification for Jeff. To completely appreciate not wanting to talk about the clinical data on Simdax. I just wanted to be clear though because you'd said in the past you did expect to file seeking a mortality claim. Is that still the case?

**Unidentified**

Well, first of all what we've said in the past is that we looked at the drug as having two potentially separate claims. One for signs and symptoms and one for mortality and our expectations on filing would obviously be based on the data that we saw and we still have the same plan going forward and like I said I really can't comment on the data.

**Unidentified**

Okay.

**Unidentified**

Thanks. We got time for one last question.

**Unidentified**

Thank you. Our final question is from Bruce Cranna. And please state your company name.

**Unidentified**

Good afternoon. It's Leerink Swann. John or Jeff, can you maybe just quickly talk about TAP -- specifically Prevsin and Lupron and I guess what I'm wondering is what's your sense. Are we approaching a point where we're getting close to stabilization with those two agents and then secondarily, actually income line looked fairly solid in the quarter, was there less sales and marketing spend in the quarter to achieve that level of profitability?

**Unidentified**

Let me comment on Prevacid and Lupron a little bit. If you look at what's happening there, actually we've been encouraged that share clearly has stabilized. Actually TRX volume is up year-over-year but price is down a little bit year-over-year so net, net Prevacid is sort of flat to very slightly down with respect to sales. Lupron's a more complicated dynamic because as you know, with the reimbursement changes, there has been a slowing down of that market. We think largely due to some physician destocking. Remember, physician stocked this product. Perhaps also due to some changes in the pattern of utilization by physicians. I think the good news there is if you look at loupe PRON shares, actually at an all-time high, about 65%. So really regained all of the share that we lost when Elgar came into the market and lowered price. Price is down, based on that. And use is down a little bit based on this reimbursement change. I think that's stabilized that's what TAP believes we're going to obviously have to see what happens with Lupron going forward into 2000 of when the reimbursement change really hits. But in -- I guess my short answer to your question is yes, we think that both products have stabilized at this point and you're starting to see that in the financial results. And our financial projections for TAP for the year as Tom mentioned remain unchanged to 425 to 450 million.

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**Unidentified**

And so I mean is it fair to characterize your position there as sort of harvesting if you will in other words this level of profitability given --

**Unidentified**

I think we're looking at two separate things going on at TAP. We have the older products Prevsin and Lupron which whether you want to call them harvesting clearly a mature stage of their lifecycle. But we also have a pipeline that has growth potential. And so that's a different sort of approach that we'll take to febuxostat in these --

**Unidentified**

And the follow on.

**Unidentified**

And the follow on to Prevacid which are coming down in the 2008 kind of time frame.

**Unidentified**

Okay. And then just a quick follow on if I could for Rick while we have him. Just on the PRISM side. Rick, do you think -- you know, I know that that instrument was somehow tied up in the -- over the years. And what's your sense global -- or rather in the U.S. share-wise? Did you have a little erosion sort of leading up to this point where you have an approval now finally for PRISM such that you expect to grab back some install-based share on PRISM and then do you have a timeline for developing Shaw GaU.S.? Thank you.

**Unidentified**

As far as the share is concerned, really in the U.S. blood bank market we did not see very much erosion at all. If you look at the quality of those assays, in the presence we had in that market it has been fairly stable. Having said that, I would tell you we have about 33 systems right now on order, our current market share assay market share in the U.S. is about 54%. We anticipate that that will go to 70% by the end of 2006 driven by PRISM. And we'll go to 90% by the end of 2007. And so this product in the U.S. will have similar impacts from a market-share standpoint than it's had in a lot of the major countries in Europe as well. So there is significant growth opportunity that will be driven by this product.

**Unidentified**

As far as Shaw Gus is concerned, we do have an active program on ShawGus. We're working through, it's not anything that I want to comment on short term, though.

**Unidentified**

Okay. Thank you. Everybody. That concludes our conference call for today. A replay of the call will be available after 12 o'clock central time on our investor relations website at [www.abbott.com](http://www.abbott.com) investor.com. That's all one word. And after 12 p.m. central time via telephone at 203-369-0662, confirmation code 2843512, the audio replay will be available until 5 p.m. on Wednesday, July 20th, and we do thank you again for joining us today investor.com. That's all one word. And after 12 p.m. central time via

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telephone at 203-369-0662, confirmation code 2843512, the audio replay will be available until 5 p.m. on Wednesday, July 20th, and we do thank you again for joining us today.

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UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

November 17, 2005

Ms. Mary L. Azcuenaga  
Heller Ehrman, LLP  
1717 Rhode Island Avenue, NW  
Washington, DC, 20036-3001

**Re: FOIA-2006-00153  
Johnson & Johnson/Abbott Laboratories**

Dear Ms. Azcuenaga:

This is in response to your 11/14/2005, correspondence requesting access, under the Freedom of Information Act ("FOIA"), to materials from the Johnson & Johnson matter, FTC File #051-0050, that show how the success or lack of success of Abbott Laboratories under the consent order will be determined. You specifically ask for the license defined in the agreement. You also ask for expedited treatment and agree to pay any fees. In accordance with the FOIA and agency policy, we have searched our records as of 11/15/2005, the date we received your request in our FOIA office.

We have located approximately 50 pages of responsive records, all of which are exempt from the FOIA's mandatory disclosure requirement as explained below. Accordingly, we are denying your request.

First, the records are exempt from disclosure under FOIA Exemption 7(A), 5 U.S.C. § 552(b)(7)(A), because disclosure of that material could reasonably be expected to interfere with the conduct of the Commission's law enforcement activities. *See Robbins Tire & Rubber Co. v. NLRB*, 437 U.S. 214 (1978).

Second, the records are exempt from disclosure under FOIA Exemption 3, 5 U.S.C. § 552(b)(3), because they are exempt from disclosure by another statute. Specifically, 15 U.S.C. § 18a(h) exempts any information or documentary material that may have been filed pursuant to the Hart-Scott-Rodino pre-merger notification program. The responsive material is additionally exempt from disclosure under FOIA Exemption 3, 5 U.S.C. § 552(b)(3), because Section 21(f) of the FTC Act provides that information obtained by the Commission in a law enforcement investigation, whether through compulsory process, or voluntarily in lieu of such process, is exempt from disclosure under the FOIA. 15 U.S.C. § 57b-2, *see A. Michael's Piano, Inc. v. FTC*, 18 F.3d 138 (2d Cir. 1994).

Third, this information contains confidential commercial or financial information, which the Commission is prohibited from publicly disclosing under both FOIA Exemption 3, by virtue of Section 6(f) of the FTC Act, 15 U.S.C. § 46f, and FOIA Exemption 4, 5 U.S.C. § 552(b)(4).

Ms. Mary L. Azcuenaga

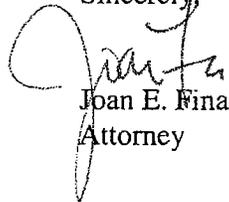
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*See National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974).

If you are not satisfied with this response to your request, you may appeal by writing to Freedom of Information Act Appeal, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington D.C. 20580, within 30 days of the date of this letter. Please enclose a copy of your original request and a copy of this response. If you believe that we should choose to disclose additional materials beyond what the FOIA requires, please explain why this would be in the public interest.

If you have any questions about the way we handled your request or about our FOIA regulations or procedures, please contact Richard Gold at (202) 326-3355.

Sincerely,

A handwritten signature in black ink, appearing to read "Joan E. Fina". The signature is stylized and cursive, with a large initial "J" and "F".

Joan E. Fina  
Attorney

November 14, 2005

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42044.0001

Federal Trade Commission  
Office of the Secretary, Room 135-H  
600 Pennsylvania Avenue, N.W.  
Washington, DC 20580

**Re: Johnson & Johnson/Guidant Corporation  
FTC File No. 051-0050  
Request that additional information be placed on the public record and that the  
public comment period be extended to thirty days following the disclosure of such  
additional information**

Dear Sir or Madam:

On November 2, 2005, the Commission announced a consent agreement in the matter of Johnson & Johnson's ("J&J") proposed acquisition of Guidant Corporation ("Guidant"). The Commission's consent agreement requires J&J to license Guidant's intellectual property surrounding the RX delivery system at no minimum price to an up-front buyer. The Commission has accepted J&J's choice of Abbott Laboratories ("Abbott") as the up-front buyer of this divestiture package.

The Commission's analysis to aid public comment states:

[T]he RX license contemplated by the proposed Consent Agreement is transferable, so that if Abbott's DES program is not successful, [Abbott] will have the incentive and ability to transfer the RX license to another firm [to ensure continued competition with J&J/Guidant].

Making the license transferable gives Abbott the ability to transfer the license to another firm but by no means standing alone provides the incentive to transfer the license and ensure continued competition. Indeed, if Abbott does not begin to commercialize its DES device by late 2007, as the Commission's consent order anticipates, or is otherwise unsuccessful, Abbott would have precisely the opposite incentive. Assuming it still wants to

succeed in the market, the last thing Abbott would want to do is to license and thereby strengthen another competitor.

Without knowing what the license may provide that would give Abbott the requisite incentive to ensure competition and without knowing how its success or lack thereof is to be determined and who would make that determination and when, it is impossible to provide meaningful comment on the order.

We therefore respectfully request that the Commission place on the public record the license with Abbott, any materials that show or discuss how Abbott's success or lack thereof will be determined, by whom the determination will be made and when, and any material that shows or bears on Abbott's incentive to license the relevant technology to another firm. We are also filing a request today for this material under the Freedom on Information Act and seeking expedited treatment (copy enclosed).

We further request that the Commission extend the comment period to and including thirty days following the placement of these materials on the public record.

Respectfully submitted,

  
Mary L. Azcuenaga

Enclosure

cc: Commissioner Thomas B. Leary  
Commissioner Jon Leibowitz  
Michael S. Wroblewski, Attorney Advisor  
Seth C. Silber, Attorney Advisor  
Susan A. Creighton, Director  
Jeffrey Schmidt, Deputy Director  
Michael R. Moiseyev, Assistant Director  
Jonathan S. Klarfeld, Esquire  
William Blumenthal, General Counsel (w/o Enclosure)  
Donald S. Clark, Secretary