

**Testimony of
The Honorable John Ashcroft
Former United States Attorney General
Chairman, The Ashcroft Group, LLC and Monitor for Zimmer, Inc.**

Good Morning. I am here today at your request to discuss policy issues associated with the use of deferred prosecution agreements. I look forward to answering the Committee's questions.

Raised in Springfield, Missouri, I attended public schools until enrolling at Yale University, where I graduated with honors in 1964. I received my Juris Doctor from the University of Chicago in 1967. Prior to entering public service, I taught business law at Southwest Missouri State University in Springfield. I co-authored multiple editions of two college law textbooks with my wife, Janet, who is also an attorney. My career of public service began in 1973 as Missouri Auditor. I was later elected to two terms as the state's Attorney General. My colleagues in the non-partisan National Association of Attorneys General elected me as their President.

I served as Governor of Missouri from 1985 through 1993. As the State's Chief Executive Officer, I balanced eight consecutive budgets, building a \$120 million budget surplus, a new rainy day fund and a \$190 million cash operating reserve. My management earned Missouri the highest triple-A rating from the three major Wall Street bond rating agencies, while Missouri's per capita state and local tax burden ranked 49th in the nation. Financial World and City and State magazines credited me with making Missouri one of the best financially managed states. In 1991, the non-partisan National Governors Association voted me Chairman.

I was elected to the U.S. Senate in 1994, where I championed greater fiscal responsibility. As a member of the Senate Judiciary and Commerce Committees, I helped to reform laws regulating the telecommunications, aviation, transportation, banking and information technology industries. In the Senate, I also served on the Labor and Human Resources Committee (now referred to as the Health, Education, Labor and Pensions Committee) which had oversight responsibility concerning Federal health care laws and policies.

President George W. Bush announced his decision to nominate me to serve as U.S. Attorney General on December 22, 2000. As U.S. Attorney General, I ran the world's largest international law firm, a national prison system and the world's finest law enforcement agencies. Relying on my executive experience, I emphasized strategic management, integrating strategic planning, budgeting and performance measurement across the Department of Justice.

As Attorney General of the United States from 2001 to 2005, I was the Chief Executive Officer of a Cabinet agency larger than most Fortune 500 corporations. In that period, the Department of Justice had 112,000 employees and an annual operating budget of \$22 billion. For the first time in its history, under my leadership, the

Department of Justice earned a clean audit opinion, a standard matched for each of the four years of my service. During my tenure as Attorney General, the Department of Justice aggressively and successfully prosecuted a wave of high-profile corporate fraud scandals and won the largest healthcare fraud cases in our nation's history. Over my four years of service, there was a 73% increase in monetary recoveries from healthcare fraud settlements and judgments, totaling nearly \$4.5 billion. In our pursuit of dozens of corporate fraud scandals, over 600 corporate criminals were convicted, including 31 Chief Financial Officers.

Today, I serve as the Chairman of The Ashcroft Group, LLC and related enterprises which provide confidential strategic consulting and crisis counseling to major international corporations. I also hold the rank of Distinguished Professor of Law and Government at Regent University.

Investigation of Zimmer, Inc. and Other Orthopedic Industry Companies

As outlined in my February 15, 2008 correspondence to the Committee, I am limited in my ability to discuss particulars of *United States v. Zimmer*, the pending criminal case in the Federal District Court of New Jersey. As the Monitor in this case, my legal duties require me to exercise impartial, independent judgment regarding the conduct of this charged defendant in the United States District Court, District of New Jersey and to assist the United States Department of Justice in the ongoing criminal investigation of the broader orthopedic industry. Certain comments about the details of these legal responsibilities would violate both my ethical responsibilities as expressed in the American Bar Association Model Rules of Professional Responsibility and under the District of Columbia Bar Association Rules of Professional Conduct.

The deferred prosecution agreement governing my responsibilities as the Monitor to Zimmer, Inc. was entered into between the United States Attorney for New Jersey and Zimmer, Inc. on September 27, 2007 (the "DPA"). The DPA defines my responsibilities to both the United States Attorney ("Office") and to the "Company", as Zimmer is referred to in the DPA. A non-exhaustive list is included at the end of this testimony.

As the Committee is aware, there are five hip and knee replacement manufacturers currently under deferred prosecution agreements and non-prosecution agreements with the United States Department of Justice. According to the Department of Justice, these companies account for nearly 95 percent of the hip and knee surgical implant industry. The goal in addressing these companies' conduct simultaneously is to ensure that the alleged illegal kick-backs to health care professionals would be eradicated industry-wide, saving American taxpayers millions of dollars. Eliminating this conduct is particularly important within the hip and knee industry because approximately two-thirds of such replacements are on patients covered by Medicare. Specifically, the

criminal complaints accuse the companies of using consulting agreements with orthopedic surgeons as inducements to use a particular company's artificial hip and knee reconstruction and replacement products.¹

The investigation leading to those agreements included work done by the Office of Inspector General at the United States Department of Health and Human Services (HHS). On February 27, 2008, Gregory Demske, the HHS Assistant Inspector General for Legal Affairs, testified before the Senate Select Committee on Aging on the breadth of this alleged conduct. These facts are important to understanding the scope and size of the responsibilities of the hip and knee replacement industry monitors. Inspector Demske stated that in 2005, the orthopedic device market for hips and knees witnessed domestic sales in excess of \$5.1 billion and worldwide sales for more than \$9.4 billion. He stated further that we [HHS] found that during the years 2002 through 2006, four manufacturers (which controlled almost 75 percent of the hip and knee replacement market) paid physician consultants over \$800 million under the terms of roughly 6,500 consulting agreements. Although many of these payments were for legitimate services, others were not. He noted that even researchers reporting in medical journals, such as the Journal of the American Medical Association and the New England Journal of Medicine, have found that such financial industry-physician relationships are pervasive and that the impulse to reciprocate for even small gifts have a powerful influence on behavior.²

Physicians who make decisions about which hip or knee replacement is implanted in patients should make those decisions solely based on what is in the best interests of those patients. A surgeon who makes decisions based on the receipt of illegal kickbacks violates his responsibility to patients, breaches the public trust, and breaks the law.

Drawing on my past professional experiences, I have built an exceptional Monitoring team of approximately 30 professionals, including lawyers, investigators, accountants, and other business consultants, to ensure enforcement of the terms of the DPA in this criminal case. These professionals include former United States Attorneys, Assistant United States Attorneys, former Federal Bureau of Investigation Special Agents, former United States Department of Justice officials serving at the very highest levels at the Department, corporate attorneys, intellectual property attorneys, former Chief Operating Officers and Chief Executive Officers of major, multi-billion dollar

¹ United States Department of Justice, U.S. Attorney, District of New Jersey, September 27, 2007 press release <http://www.usdoj.gov/usao/nj/press/index.html>.

² "Examining the Relationship between the Medical Device Industry and Physicians" Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, before the Senate Special Committee on Aging, February 27, 2008.

corporations. Many of these professionals carry degrees from the nation's best institutions including: Yale, Yale Law School, Harvard Business School, Harvard Law School, the University of Virginia Law School, Wharton Business School, Georgetown Law School, Vanderbilt Law School and the University of Chicago Law School.

Deferred Prosecution Agreements and Federal Monitor Involvement – Background

Deferred prosecution agreements (DPA or Agreement), or pretrial diversion programs, have a long history in the United States system of justice. Under an Agreement, the prosecutor files a criminal complaint against a defendant. However, the prosecution of that complaint is deferred while the defendant complies with the terms of the Agreement. Once the terms of the Agreement have been met, usually after a set period of time, the prosecutor seeks dismissal of the criminal charges. The terms are usually significant and require the corporate defendant to take systemic remedial measures and to cooperate with the ongoing criminal investigation.

Deferred prosecution agreements originally were used in the context of juvenile offenders so they would not suffer the long term consequences associated with a criminal conviction or guilty plea. The same theory applies to the use of such Agreements in the corporate context. Collateral damage, or externalities, associated with a corporation under the cloud of a Federal indictment or conviction are severe, or even fatal. That is particularly true for a corporation which is highly regulated, has significant government contracts or whose business is dependent upon a reputation of corporate integrity.

It is my understanding that the United States Department of Justice entered into its first Agreement with a corporate defendant in 1992 in the Salomon Brothers case. In the late 1990s and early 2000s corporate scandals began to threaten the stability and worldwide trust of the United States economy. The corporate abuses led to the formation of the President's Corporate Fraud Task Force and made uncovering and prosecuting corporate fraud a government-wide priority.

The Corporate Fraud Task Force resulted in a significant increase in prosecutions. As previously stated, during my tenure as the Attorney General, 600 corporate criminals were convicted, including 31 Chief Financial Officers. In addition, these prosecutions reminded prosecutors and policy makers of the significant collateral damage resulting from a Federal indictment. Before being indicted for its alleged wrongdoing in the Enron scandal, Arthur Andersen was an American accounting icon with annual worldwide revenues of \$9.3 billion and over 25,000 employees. Following the indictment the company collapsed and those 25,000 employees lost their jobs. In working with the Corporate Fraud Task Force it became clear to me that while

addressing past criminal conduct was important, changing the corporate culture that led to the activity was necessary to prevent the offensive conduct from reoccurring.

The second deferred prosecution agreement was entered into in 1994 with Prudential Securities.³ The Prudential Securities case was the first time the United States Department of Justice made retaining a monitor a condition of the agreement. In the five years following the Prudential Securities case, the Department of Justice continued to use deferred prosecution and non prosecution agreements as a tool to address corporate wrongdoing and misconduct. In 1999, the Department issued guidance in the form of what is commonly referred to as the "Holder Memo."⁴ This guidance memorandum was drafted by Eric Holder, Jr., the Deputy Attorney General of the Department of Justice. It stated, in part, that prosecutors should consider the following eight factors in determining whether to charge a corporation for corporate fraud or other wrongdoing:

- Nature/seriousness of offense
- Pervasiveness of wrongdoing
- Prior conduct of company
- Whether company voluntarily disclosed wrongdoing and its willingness to cooperate in investigation
- Adequacy of company's pre-existing compliance program
- Remedial actions of company to deal with wrongdoing
- Impact a prosecution may have on innocent third parties, such as shareholders, pension holders and company employees
- Alternative mechanisms of prosecutors to punish company

The above eight factors were echoed four years later in a memorandum entitled "Principles of Federal Prosecution of Business Organizations," better known as the "Thompson Memo," issued by the then-Deputy Attorney General Larry D. Thompson in

³See Vikramaditya Khanna & Timothy L. Dickinson, *The Corporate Monitor: The New Corporate Czar?*, 105 MICH. L. REV. 1713 (2007).

⁴ See Memorandum from Eric Holder, Deputy Attorney General, Department of Justice, to Component Heads and United States Attorneys, *Bringing Criminal Charges Against Corporations* (June 16, 1999).

January 2003, which reiterated the above considerations while adding a ninth factor, company cooperation.⁵

The Department of Justice's current stance on corporate prosecution and the use of corporate monitors is enunciated in a memorandum issued on December 12, 2006 by U.S. Deputy Attorney General Paul J. McNulty, which was designed to supersede and replace the guidance contained in the Thompson Memo.⁶

As noted in the Department of Justice's press release regarding the McNulty Memo, the guidance contained therein continues to require consideration of the factors denoted in the Thompson Memo but adds new restrictions for prosecutors seeking privileged information from companies. Specifically, the Department created new approval requirements that federal prosecutors must comply with before they can request waivers of attorney-client privilege and work product protections from corporations in criminal investigations. The McNulty Memo instructs federal prosecutors that waivers of the attorney-client privilege can only be sought when there is a "legitimate need." He states further that when federal prosecutors seek privileged attorney-client communications or legal advice from a company, the U.S. Attorney must obtain written approval from the Deputy Attorney General.⁷

A general principle noted in the McNulty Memo concerns the Department's philosophy regarding the prosecution of companies. As stated therein, "[c]orporations should not be treated leniently because of their artificial nature nor should they be subject to harsher treatment. Vigorous enforcement of the criminal laws against corporate wrongdoers, where appropriate, results in great benefits for law enforcement and the public, particularly in the area of white collar crime. Thus, while prosecutors must apply the same factors in determining whether to charge a corporation as they do with respect to individuals, due to the nature of the corporate person, prosecutors conducting an investigation, determining whether to bring charges, and negotiating plea agreements, must consider the factors previously outlined in the Holder Memo, as amended by the Thompson Memo, in reaching a decision as to the proper treatment of a corporate target.

⁵ See Memorandum from Larry D. Thompson, Deputy Attorney General, Department of Justice, to Heads of Department Components, U.S. Attorneys, Principles of Federal Prosecution of Business Organizations (January 20, 2003).

⁶ See Memorandum from Paul J. McNulty, Deputy Attorney General, Department of Justice, to Heads of Department Components, U.S. Attorneys, Principles of Federal Prosecution of Business Organizations (December 12, 2006).

⁷ Department of Justice Press Release: "U.S. Deputy Attorney General Paul J. McNulty Revises Charging Guidelines for Prosecuting Corporate Fraud", December 12, 2006.

In connection with this effort, Deputy Attorney General Paul J. McNulty was quoted as saying, "Our efforts to investigate and prosecute corporate fraud in the past five years through [President Bush]'s corporate initiative have been tremendously successful. With this new guidance, we want to encourage corporations to prevent corruption through self-policing and continue to punish wrongdoers through cooperation with law enforcement."

In addition to preserving innocent employee jobs, deferred prosecution agreements are thought to provide an opportunity to preserve shareholder value and company market share. They provide defendant companies with legal and business guidance on how to conduct their businesses legally and ethically. They do this at the expense of the offending business and thereby free Department of Justice resources to prosecute other law-breaking companies. A deferred prosecution agreement allows a company to maintain operations while rectifying previous wrongdoing or unlawful behavior and allows the Department of Justice to resume prosecution in the event a company fails to comply with its deferred prosecution agreement responsibilities.

A Federal monitor has a unique and critical role in the deferred prosecution agreement structure. One hundred percent of the monitor's fees are paid for by the defendant company. This system has been designed to place the cost of compliance onto the defendant company rather than further burdening American taxpayers with the cost of rectifying any improper, fraudulent, or illegal activity.

The fact that no taxpayer money is spent on monitor's fees helps insulate a monitor from political pressure. A monitor and the monitor's team is a force multiplier for the investigators, prosecutors, and regulators to ensure ongoing and meaningful changes are made by a company. This protects the public and the corporate stakeholders' interest much better than just allowing a company to pay a large fine and agree to systemic changes without any ongoing oversight.

While a monitor assists the prosecutor in the ongoing criminal investigation, the monitor also is responsible for ensuring that the company has systems and processes in place to reduce the likelihood that the conduct subject to the criminal complaint will occur in the future. My current monitoring responsibilities are unique in this respect. Because this investigation involves an entire industry, the monitors involved in these five deferred prosecution and non-prosecution agreements have an additional responsibility of not only investigating their own companies, but also assisting in the investigations of the other orthopedic manufacturers and providers. The investigations also include investigating health care professionals benefiting from improper arrangements.

Monitor Responsibilities and Authorities under September 27, 2007 Deferred Prosecution Agreement /Non Prosecution Agreements

To address, as precisely as possible, the Monitor's responsibilities and authorities, below is a non-exhaustive list of such responsibilities under the Deferred Prosecution Agreement which guides my work.⁸ These are public documents relating to the monitorship for which I have responsibility. Because they are matters of public record and not law enforcement sensitive information, I am providing concepts from those documents as illustrations of the nature of modern monitorship.

Generally, the DPA requires that Zimmer retain an outside, independent individual (the Monitor) selected by the Office, *after consultation with the Company*, to evaluate and monitor the Company's compliance with the DPA. In addition to evaluating and monitoring the Company's compliance with every aspect of the DPA, the Agreement requires that the Monitor fulfill the following additional responsibilities and gives the Monitor the following authorities. The Monitor shall:

1. Have access to all non-privileged Company documents and information the Monitor determines are reasonably necessary to assist in the execution of his or her duties.
2. Receive notification by the Company of any credible evidence of criminal conduct or serious wrongdoing relating to federal health care laws by the Company, its officers, employees and agents.
3. Receive all relevant non-privileged documents and information concerning such allegations,
4. Review and evaluate all Company policies, practices, and procedures relating to compliance with the Deferred Prosecution Agreement and the below subjects. Report and make written recommendations relating to compliance with the DPA and those same subjects:
 - A. Review corporate structure and governance relative to selecting, engaging and paying consultants;
 - B. Review the effectiveness of the company's procedures and practices to select, engage and pay consultants and the related legal, compliance,

⁸ The Deferred Prosecution Agreement entered into between the United States Attorney's Office for the District of New Jersey and Zimmer, Inc. on September 27, 2007 is available at <http://www.usdoj.gov/usao/nj/press/files/pdf/Deferred%20pros%20agreementZimmerfinal.pdf> and www.zimmer.com.

research and development, marketing, sales, internal controls, and finance functions;

C. Review the effectiveness of the company's training and education programs in federal and state health care laws concerning relationships between the Company and consultants; Medicare, Medicaid, and other health care benefit programs; ethics; and compliance and corporate governance issues relating to federal and state health care laws;

D. Review the structure and content of agreements memorializing arrangements to engage and pay Consultants in exchange for the provision of Services the Company, and the Company's payments to Consultants made thereunder. The Monitor shall have access to and may review all previously entered agreements to the extent he or she reasonably deems necessary; and

E. Review the influence, actual or potential, over consultants's selection of the Company's product as a result of the financial relationships between consultants and the Company.

5. Monitor and review the company's compliance with the DPA and all applicable federal and state health care laws, statutes, regulations, and programs, including the Anti-Kickback Statute, relating to the sale and marketing of hip and knee reconstruction and replacement products.

6. Cooperate with federal agencies and provide information about the Company's compliance with the DPA.

7. Provide written reports to the Office [U.S. Attorney of the District of New Jersey] on a quarterly basis, beginning in January 2008

8. Make recommendations to the Company to take any steps deemed reasonably necessary for compliance with the DPA and to enhance the Company's future compliance with federal and state health care laws as related to the sale and marketing of joint reconstruction and replacement products, and require the Company to take such steps when it is agreed that they are ~~reasonable~~ and necessary for compliance with the DPA.

9. Retain, at the Company's expense (after consultation with the Company and the Office) consultants, accountants or other professionals deemed ~~reasonable~~ necessary+

10. Monitor and approve the Company's Annual Needs Assessment (the Annual Needs Assessment determines the reasonable needs for educational consulting services and new product-development consultants).⁹

11. Approve modifications to that Annual Needs Assessment.

12. Review consultant contracts before the Company's 2008 Annual Needs Assessment is approved. Specifically, the Monitor shall:

- Review and approve all new or renewed consulting agreements;
- Review, in the Monitor's discretion, any requests for consulting services; and
- Review, in the Monitor's discretion, any payments made to consultants

13. Review consultant contracts executed after the Company's 2008 Annual Needs Assessment is approved. Specifically, the Monitor shall:

- Review and approve all new consulting agreements;
- Review, in the Monitor's discretion, any renewal of a consulting agreement;
- Review, in the Monitor's discretion, any requests for consulting services; and
- Review, in the Monitor's discretion, any payments made to consultants

14. Review, in the Monitor's discretion, any payments made to Continuing Medical Education (CME), reimbursement specialists, any non-physician engineering or marketing consultants, or any person excluded from the definition of "Consultant" in the DPA.

15. Review, in the Monitor's discretion, any payments made to consultants as honoraria, fellowships, gifts, donations, charitable contributions and other non-service payments.

⁹ United States Department of Justice, U.S. Attorney, District of New Jersey, September 27, 2007 press release <http://www.usdoj.gov/usao/nj/press/index.html>

15. Review and approve any new or substitute consultants.

16. Approve any changes to the hourly rate or any payments [to consultants] made at a rate other than the hourly rate established by the DPA.

17. Monitor the consultant [website] disclosure obligations of the Company.

18. Monitor the information received by the Company's confidential hotline and e-mail. Follow up and investigate any allegations of wrongdoing or criminal activity.

19. Prohibit the Company from entering into any consultant agreement deemed to violate the DPA.

20. Evaluate each new consultant to be considered for a consulting agreement.

21. Approve the Company's standard form for documentation and verification of consulting services provided.

22. Approve any direct compensation or remuneration to consultants.

23. Ensure that the aggregate royalties paid per project to all Consultants do not exceed fair market value.

24. Approve Company processes to review individual Consultant contributions on product development teams to ensure that intellectual property has been provided by the Consultant.

25. Review Company determinations whether intellectual property has been provided, determine whether royalty based contracts are reasonable in duration. Approve the identification of royalty-bearing products.

26. Approve the Company's mandatory participants for required training.

27. Approve the Company's corporate integrity and legal training programs.

This list of responsibilities guides my daily work and that of my monitoring team. It drives our deadlines and our priorities. However, this list reflects just a fraction of a monitor's duties. Because DPAs also require a monitor to determine a company's compliance with all of the requirements under the DPA, to fully appreciate the breadth and scope of all of a monitor's responsibilities you should also review the company's obligations under a DPA.

I believe this list of monitor responsibilities is significantly characteristic of previous deferred prosecution agreements. Each agreement addresses a unique set of facts, corporate culture, and challenges. Not only do the circumstances of various monitorships differ, the requirements specific to a monitorship evolve depending on the level of cooperation by the charged entity and the broad range of remedial strategies which may be employed. As a monitor fulfills his or her obligations, some responsibilities become more important and more time consuming while others take on a less significant role.

It is my hope that the Committee will gain a clear understanding of the policies associated with Deferred Prosecution or Non-Prosecution Agreements at the Department of Justice. It also is my hope that the Committee will understand the responsibilities of monitors generally. I look forward to answering your questions.