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MARKETING OR MEDICINE: ARE DIRECT-TO-CONSUMER DEVICE ADS PLAYING DOCTOR?

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BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

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MARKETING OR MEDICINE: ARE DIRECT-TO-CONSUMER MEDICAL DEVICE ADS PLAYING DOCTOR?

WEDNESDAY, SEPTEMBER 17, 2008

U.S. SENATE
SPECIAL COMMITTEE ON AGING
Washington, DC.

The committee met, pursuant to notice, at 10:29 a.m. in room SD–562, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl [presiding], and Salazar.

OPENING STATEMENT OF SENATOR HERB KOHL

The CHAIRMAN. Good morning to one and all. We'll commence our hearing at this time. We thank our witnesses for being with us today.

Today we're examining issues related to direct to consumer advertising for restricted medical devices that are regulated by the Food and Drug Administration. This is part of an ongoing 15 month series of oversight hearings we have held on medical device and pharmaceutical marketing. Unlike direct-to-consumer advertising of drugs, direct-to-consumer advertising of medical devices has not yet been highly scrutinized.

Since the mid–1990's when the Federal Government changed rules regulating such advertising the drug industry has spent billions of dollars advertising their products directly to consumers. The FDA has devoted considerable resources to the oversight of direct-to-consumer pharmaceutical advertising. There have been several Congressional hearings held on this practice.

However, the medical device industry is just beginning to get into the game. Over the past four or five years their use of DTC ads is growing on television, in print and on the internet. Hundreds of millions of dollars have been spent on them according to the Congressional Research Service.

While their spending on direct-to-consumer ads is still only a fraction of drug industry spending, this marketing practice is growing. In recent years a number of DTC ad campaigns have been launched in an effort to market specific and often complex medical device products, some of which require surgery to obtain. As with DTC drug ads the FDA has raised concerns about advertising restricted medical devices, specifically about whether appropriate risk and safety information is provided to consumers including seniors and the elderly.

Today we'll hear from a variety of medical, advertising and consumer experts. They will detail for the Committee perceived shortcomings in DTC advertisements for medical devices and how these ads can influence consumers and patients. Our witnesses also will outline recommendations on how we might improve the review and the oversight of these ads.

We will hear from the head of the FDA's medical device center about how the Agency oversees these DTC medical device ads. As well as how those methods differ from the more extensive FDA efforts to track and analyze DTC drug ads.

We've also invited AdvaMed to testify this morning. AdvaMed is the largest medical device industry organization and will weigh in on the question of regulating DTC medical device ads.

We should note that in 2006 the American Medical Association announced its support for enhanced regulation of DTC ads by the FDA and went so far as to call for a moratorium on all new DTC ads until physicians have been appropriately educated about the drug or the medical device.

Based on what we hear here today we are prepared to work with Chairman Dingell in the House to consider similar legislative measures. We want to acknowledge that DTC advertising may have some benefits. Responsible DTC advertising can encourage consumers and patients to become proactive in their own treatment plan and encourage a wide audience to consider preventive medicine. These are positive and potentially valuable aspects of DTC advertising.

So we thank our witnesses. We welcome them here today. Introducing the members of the first panel.

Our first witness will be Dr. Kevin Bozic. Dr. Bozic is an Associate Professor in residence in both the Department of Orthopedic Surgery and the Institute for Health Policy Studies at the University of California in San Francisco. He's conducted studies on how direct-to-consumer advertising of restricted medical devices does have the potential to adversely impact the doctor/patient relationship, patient education, health care costs as well as health care quality. He's speaking today on behalf of the American Association of Orthopedic Surgeons.

Our next two witnesses will share their time jointly. Dr. William Boden is Director of Cardiovascular services at Kaleida Health System in Western New York and Chief of Cardiology at Buffalo General and Millard Fillmore Hospitals in Buffalo.

Dr. George Diamond is a 2004 recipient of the Distinguished Service Award of the American College of Cardiology and is the author of hundreds of peer reviewed publications. Dr. Boden and Dr. Diamond are the authors of a recent article in the New England Journal of Medicine which offers a detailed critique of a particular heart stent advertisement that was broadcast to millions of Americans.

Also joining us here today is Professor Ruth Day, the Director of the Medical Cognition Laboratory at Duke University and a Senior Fellow at the Duke Aging Center. Dr. Day has served on many FDA Advisory Committees and was also a Fellow at the Center for Advanced Study in the Behavioral Sciences. Her research is on

comprehension and memory for medical information, especially drugs and medical devices.

Our last witness on our first panel will be Ami Gadhia who is a Policy Counsel for Consumers Union, a non-profit publisher for Consumer Reports magazine. Consumers Union is an independent, non-profit organization that advocates on behalf of consumers in many fields of industry including healthcare.

We welcome you all here today. Dr. Bozic, you may testify.

STATEMENT OF KEVIN BOZIC, M.D., PROFESSOR OF ORTHOPEDIC SURGERY, UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO, CA

Dr. BOZIC. Thank you. Good morning, Chairman Kohl and other distinguished members of the Committee. My name is Dr. Kevin Bozic and I speak to you today as a practicing orthopedic surgeon and health care services researcher from the University of California, San Francisco and a member of the Board of Directors of the American Association of Orthopedic Surgeons. On behalf of the AAOS, I thank you for providing me the opportunity to testify to you today on the issue of direct-to-consumer advertising of restricted medical products.

As you've indicated, over the past decade the United States has experienced a dramatic increase in direct-to-consumer advertising from medical device and pharmaceutical manufacturers, health plans, hospitals and physicians, all attempting to increase their market share by advertising their products and services directly to patients. The internet has created a new generation of technologically savvy and empowered health care consumers who are taking a more active role in finding the best solutions for wellness and health. We encourage our patients and their families to obtain and understand evidenced based health care information. We encourage patients to work with their healthcare practitioners to develop shared decisionmaking for treatments that promote cost effective healthcare.

We believe that direct-to-consumer advertising of restricted medical products has the potential for both positive and negative consequences. Direct-to-consumer advertising may encourage patients to seek treatment for previously undiagnosed disease, and may destigmatize certain diseases or health conditions, help create more informed patients and foster true shared decisionmaking between patients and their physicians.

However, we're also aware of the potential negative consequences of DTCA related to medical products. Product specific advertisements which exaggerate the benefits and downplay the risks of a medical device may strain the doctor/patient relationship by creating unrealistic patient expectations, thus diminishing the role of the physician in clinical decisionmaking. Furthermore, patient pressure in response to direct-to-consumer ads may lead to over utilization of costly, at times unproven, medical devices and may lead physicians to venture outside their comfort zone in order to satisfy inappropriate patient requests for specific treatments or devices.

In the course of today's discussion, we would note that disease awareness or help seeking advertising, which seeks to raise aware-

ness amongst patients regarding a specific disease state or health condition should be differentiated from product specific advertising. The AAOS holds patient education as one its most important objectives. We believe that help seeking advertising may stimulate patients to research their health conditions and discuss all available options with their healthcare practitioners. We recognize that delayed diagnosis and treatment of certain chronic disease conditions such as arthritis and osteoporosis are serious health concerns in the U.S., and disease awareness advertisements may play a vital role in bringing needed therapies to patients with chronic diseases.

Although the effects of direct-to-consumer advertising related to pharmaceutical drugs have been studied extensively, there are substantial differences between pharmaceutical products and medical devices which make extrapolating the findings or conclusions from studies regarding the effects of DTCA related to drugs to the potential impact of advertising that is used to promote regulated medical devices inappropriate and misleading.

First, there's a substantial cost differential between medical devices and prescription drugs.

Second, medical devices are usually sold to hospitals, although physicians are the primary decisionmakers and end users. Unlike prescription drugs, early adopters of new medical technologies, including physicians and hospitals, often promote their use of these technologies in an attempt to differentiate themselves in a competitive marketplace. However, when a physician decides to use a new device in their practice additional training is often recommended and the potential adverse consequences to the patient and the physician are considerable if an inappropriate or unfamiliar device is used.

Finally, unlike prescription drugs, the choice of implant or procedure cannot easily be substituted if the result of the procedure is undesirable.

We're concerned about the lack of fair balance and risk information in direct-to-consumer ads related to medical devices. Potential benefit information is typically presented in layman's terms whereas risk information is down played by using medical jargon, using a very small font size or increasing the speed of delivery of information in a voice over announcement. Therefore risk information is often not read, not comprehended nor sometimes even reasonably visible.

In a 2007 published study on the impact of direct-to-consumer advertising in orthopedics, my colleagues and I evaluated the influence of DTCA in orthopedics by surveying practicing orthopedic surgeons who perform hip and knee replacement procedures and patients who were scheduled to undergo these procedures. The goals of our study were to evaluate the impact of DTCA on consumer demand, healthcare services, resource utilization and the doctor/patient relationship. We found that although direct-to-consumer ads had a substantial influence on both patient and surgeon decisionmaking, patients and surgeons differed considerably with respect to their opinions of the value of DTCA as a source of information regarding hip and knee replacement surgery.

The majority of surgeons surveyed believed patients who were exposed to DTCA were confused or misinformed about the appro-

priate treatment for their condition, had unrealistic expectation regarding the benefits of the specific type of surgery or implant and requested types of surgeries or implants that were not appropriate for their conditions.

In contrast, the majority of patient respondents believed that advertisements educated them about their medical conditions and treatment options. Only 18 percent of patients thought advertisements confused them about the appropriate treatment for their condition.

The findings of our study underscore the need to improve the quality and accuracy of information available to patients regarding their health conditions and treatment options.

As surgeons, we applaud efforts by our patients to educate themselves regarding their health conditions and their potential treatment options. However, we believe it is important for patients to evaluate the source and accuracy of the information on which they base their opinions.

Reliable healthcare information that is supported by scientific evidence has the potential to enhance the dialog between patients and their physicians, and to improve patient satisfaction and the overall quality and efficiency of the care we deliver. However, as our research has shown biased information contained in direct-to-consumer advertisements promoting specific regulated medical devices which are not supported by scientific evidence has the potential to cause tremendous harm to the doctor/patient relationship, to create unrealistic patient expectations and to lead to inappropriate over utilization of costly, unproven medical technologies which could have dire public health consequences.

In closing we offer the following specific recommendations to the Committee as it examines the consequences of direct-to-consumer advertising of restricted medical products.

We believe that direct-to-consumer advertising of medical devices has the potential to create distorted markets and have adverse public health consequences, and therefore we support greater restraint from the medical device industry and greater oversight from the FDA.

We support ongoing research into the effects of direct-to-consumer advertising on the physician/patient relationship, healthcare services resource utilization and spending, public safety and cognitive science.

We support disease awareness and help seeking advertisements which seek to educate patients about their health conditions and the treatment options available to them rather than product specific advertising. Claims made in product specific advertisements related to medical devices are often biased, not supported by scientific evidence and contribute to unrealistic patient expectations and inappropriate requests for specific procedures or implants which could have great public health consequences.

We support the presentation of fair, balanced and risk and benefit information in direct-to-consumer ads of regulated medical devices. We recommend that healthcare stakeholders work together to improve the quality and accuracy of information contained in consumer directed advertisements related to medical products.

We support increased resources for the FDA in the area of medical device advertising and increased oversight from the FDA's Center for Devices and Radiological Health advertising review staff on the DTCA of medical devices.

Finally, we support a prohibition of direct-to- consumer advertising and marketing on restricted medical products to children.

I appreciate the opportunity to share our views with the Committee on the issues related to direct-to-consumer advertising of restricted medical devices. I look forward to answering any questions you may have.

[The prepared statement of Dr. Bozic follows:]

Statement

of

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Chair, Health Care Systems Committee
American Association of Orthopaedic Surgeons
(AAOS)
American Association of Hip and Knee Surgeons
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on

Marketing or Medicine: Are Direct-to-Consumer Medical Device Ads Playing Doctor?

Presented to the
Special Committee on Aging
U.S. Senate

September 17, 2008

Good morning, Chairman Kohl, Ranking Member Smith and other distinguished members of the committee. My name is Dr. Kevin Bozic, and I speak to you today as a practicing orthopaedic surgeon and a health care services researcher from the Department of Orthopaedic Surgery and the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco.

I am also a member of the Board of Directors for the American Association of Orthopaedic Surgeons (AAOS) and the American Association of Hip and Knee Surgeons (AAHKS), and Chair of the AAOS Health Care Systems Committee. On behalf of the AAOS and the AAHKS, I thank you for providing me the opportunity to testify before you today on the issue of direct-to-consumer advertising (DTCA) of medical devices. This issue is of particular interest to me both as a practicing clinician and as a health care services researcher, and during the course of my testimony I will be referring to a 2007 study which I authored on the impact of direct-to-consumer advertising in orthopaedics.[1] The DTCA of medical devices and is just beginning to be scientifically studied, and there is sparse data in the published literature. This type of advertising proliferates on television, in print media such as newspapers, magazines, billboards, as well as on the Internet.

Overview of Marketing in Medicine

The Food and Drug Administration (FDA) regulation of DTC advertising began with the Federal Food, Drug and Cosmetic (FD&C Act) of 1938. However, prior to 1980, pharmaceutical manufacturers and representatives primarily directed their marketing efforts to health care professionals.

During the 1980's, the first print pharmaceutical advertising designed for consumers was distributed. The FDA instituted a moratorium on this practice in 1983, which was eventually lifted in 1985.[2] However, pharmaceutical companies did not resume DTC advertising efforts until around 1990. In 1997, the FDA issued a draft guidance document and a final guidance in 1999[3] on consumer-directed broadcast advertisements. The Agency required that advertising of medical products must not be false, misleading, or lacking in material fact. Additionally, the guidance stated that advertisements must present a fair balance of the risk and benefit information.

The 1999 guidance applies to marketing efforts for product specific advertising for prescription human and animal drugs and biological products for humans. The consumer-directed broadcast advertisement guidance is not intended to address the advertising of medical devices. As soon as this guidance was finalized, DTCA efforts increased significantly in 2000 and included the advertising of medical devices and technologies to orthopaedic consumers and patients.

Over the past decade, DTCA has increased dramatically with advertisements from medical device and pharmaceutical manufacturers, over-the-counter drugs, hospitals, insurers, providers, and fitness centers[4] all attempting to increase their market share.

In February of 2004, the FDA issued the first guidance for the DTCA of restricted medical devices.[5] At the same time, the FDA issued a guidance document on "help-seeking" communications by or on behalf of drug and device firms[6] in addition to a guidance document on the brief summary requirements for DTCA to disclose risk information in print media.[7]

DTCA offers manufacturers the opportunity to promote products and services directly to the patient, bypassing all other parties involved in the decision and authorization chain. When manufacturers advertise directly to the patient, it is the patient who then demands the product from their surgeon, who in turn makes a product demand of the manufacturer. While marketing activities are not always 100% successful, directing the marketing efforts to the larger audience will drive demand for the product to the surgeon through the patient.[8]

Proponents argue that DTCA offers many benefits by enhancing patient education efforts to create more informed patients, empowering patients with information regarding their health conditions and potential treatment options, de-stigmatizing certain health conditions, calling attention to untreated disorders, encouraging efficient dialogue between patients and physicians, and encouraging treatment adherence and compliance with treatment plans. Conversely, opponents claim that DTCA does not educate consumers, because the information contained in DTC ads is biased and misleading, and benefits of the drug or device are exaggerated and risks are at best downplayed.[6]

Additionally opponents argue that DTCA significantly strains the doctor-patient relationship by increasing the length of office visits and diminishing the role of the physician in clinical decision making.[9, 10] Opponents also contend that patient pressure could lead to excessive or inappropriate resource utilization and that clinicians could be led to venture outside their "comfort zone" in order to satisfy inappropriate patient requests for specific treatments.[2,9, 10, 11]

The AAOS continues to have concerns about the DTCA of restricted medical products. In 2004, AAOS appointed a Board of Directors level Task Force and issued a position statement on device and drug DTCA issues. The AAOS continues to examine DTCA and its subsequent effects on the physician-patient relationship and believes in the primacy of the physician-patient relationship. Physicians and patients are partners in health care and must reach informed decisions together.

"Help-seeking" Advertising

"Help-seeking" advertising should be differentiated from specific product endorsement advertising and may provide patients with useful educational information. The AAOS holds patient education as one of its most important objectives. *Your Orthopaedic Connection* on the AAOS' home page is an objective information source for patients, containing diagrams, text, and brochures written specifically for patients. Additionally, the AAOS has produced many patient education videos to generate a dialogue between patients and surgeons about what patients can anticipate during fracture care, joint

replacement surgery, or during the treatment of soft tissue injuries, amongst other orthopaedic procedures.

The National Institutes of Health (NIH) consensus conferences on Total Knee Replacement (2003) and Total Hip Replacement (1994) found strong evidence of disparities between racial and ethnic groups in content knowledge and surgical rates and that these underutilized therapies could greatly enhance the quality of life. According to a consensus report published by the NIH in 2004, only 9% to 13% of patients who potentially could benefit from a joint arthroplasty actually receive this highly effective treatment.[12] The AAOS realizes that there are significant health disparities in the U.S. and that education plays a vital role in bringing needed therapies to patients. "Help-seeking" advertising may aid in generating educational material and stimulate a patient to research their health condition and seek all available options with their health care practitioners.

Differences between DCTA of drugs and DCTA of devices

Although the effects of DTCA related to drugs have been studied extensively, there are substantial differences between DTCA related to pharmaceutical products and medical devices which make extrapolating the findings or conclusions inappropriate and misleading. First, there is a substantial difference in price between medical devices and prescription drugs. Second, medical devices are usually sold to hospitals, although surgeons are the primary decision makers and end users. Unlike prescription drugs, early adopters of new medical technologies, including physicians and hospitals, often promote their use of these technologies in an attempt to differentiate themselves in a competitive marketplace to attract patients who seek treatment from "high tech" or "cutting-edge" providers. However, when a surgeon decides to use a new device in their practice, additional training is often recommended, and there is a learning curve effect that can be associated with a higher rate of complications. Finally, the potential adverse consequences to the patient and the surgeon are considerable if an inappropriate or unfamiliar device or surgical technique is used, the choice of implant or procedure cannot be easily substituted if the result of surgery is unfavorable.

DTCA of devices may not inform patients about the differences in product design, composition of materials, strength of the devices, or proper clinical indications. Potential patients may not have access to post-market surveillance data or understand issues relating to device performance and safety. Surgeons choose devices to meet an individual patient's needs. For example, implant wear is a significant issue with devices used by orthopaedic surgeons. Patients may not be aware of the appropriateness of certain devices for their particular health conditions or health status.

There is considerable variability in medical devices beyond the FDA's Class I, II, and III distinctions. Some medical devices dissolve within the body, such as wrinkle fillers, other devices can be applied to the surface of the body and are removable, such as contact lenses, while many devices are surgically implanted and may be intended to reside within the patient for the lifetime of the patient. Surgically implanted devices have the gravest

consequences for the patient and surgeon should the device prove to be less than optimal. Nonetheless, the AAOS is not aware that the FDA makes that type of distinction when reviewing product advertising.

DTCA lacks fair balance of benefit and risk information

The practice of marketing medical devices directly to the consumer rather than to the physician has become the subject of significant debate. Many advertisements are incomprehensible to the American public, which studies have shown on average read at an eighth grade reading level.[13] Most information, particularly in print advertisements, is edited from the FDA approved labeling requirements targeted to health care professionals. Side effects and risk information are often formatted on the back of a print advertisement and are therefore, generally neglected by readers. Additionally, the font size of the print advertisement is significantly smaller when conveying risk information as opposed to the benefit information. Smaller font size is particularly difficult for seniors to read as their vision becomes less acute during the aging process.

The lack of fair balance in describing benefit and risk information in advertising is problematic. Potential benefit information is typically presented in layman's terms whereas risk information is downplayed by using medical jargon, using a very small font size, or increasing the speed of delivery of information in a voice-over announcement. Therefore, risk information is often not read, not comprehended, nor sometimes even reasonably visible.

Increased spending, utilization, and sales

Increasing procedure volume and costly new implant technologies have led to concerns among health policy makers regarding the costs associated with hip and knee replacement procedures, which currently represent the largest single procedural cost in the Medicare budget. As mentioned previously, the literature on DTC marketing and advertising of medical devices is just beginning to accrue. However, if we examine the published literature on drugs, we find evidence of the DTCA of drugs increases pharmaceutical sales.[14]

In 2005, U.S. health care spending grew 7.4 % to over $2 trillion dollars; much of that growth was attributable to increased spending on prescription drugs. Increased drug spending is due to three factors: increased utilization, increased prices, and the use of new, expensive medications.[15] DTCA is relegated to a concentrated subset of medications which tend to be the best selling drugs[16] with the top ten drugs accounting for 36 % of all DTCA spending in 2001.[17] According to a 2002 Government Accountability Office report, DTCA increases prescription drug sales and utilization.[18] DTCA also increases the sales in the entire class of drugs. For example, prescription drugs used to treat allergies would all increase in sales in response to the DTC advertisement of one allergy medication.

In a time of necessary fiscal responsibility, David M. Walker, former Comptroller General of the U.S., in testimony before the Budget Committee of the House of Representatives, listed health care expenditures as the biggest driver of the long-term fiscal challenge facing this nation.[19] In light of the national expenditure on Medicare Part D benefits, the cost-effectiveness of pharmaceutical medications is particularly important for long-term fiscal considerations.

DTCA in Orthopaedics

In our 2007 published study,[1] my co-authors and I evaluated the influence of DTCA in orthopaedics by surveying practicing orthopaedic surgeons who perform hip and knee replacement procedures and patients who where were scheduled to undergo hip or knee replacement surgery. The goals of our study were to evaluate the impact of DTCA on consumer demand, health services resource utilization, and the doctor-patient relationship in orthopaedics, including patient and surgeon awareness of and exposure to DTCA, their level of satisfaction with the quality and accuracy of information provided in DTCA, and their general opinions of the value of DTCA.

We found that DTC ads had a substantial influence on both patient and surgeon decision making. However, we also found that patients and surgeons differed considerably with respect to their opinions on the value of DTCA as a source of information regarding hip and knee replacement surgeries. The majority of surgeons believed patients who were exposed to DTCA were confused or misinformed about the appropriate treatment for their condition, had unrealistic expectations regarding the benefits of a specific type of procedure or implant, and requested types of surgery or implants that were not appropriate for them, whereas less than 1/3 of surgeon respondents believed patients who were exposed to DTCA were more educated regarding their condition or their treatment options.

In contrast, the majority of patient respondents believed advertisements educated them about their medical conditions and helped make them more aware of new technologies, joint implants, or types of surgeries, and only 18% of patients thought advertisements confused them about the appropriate treatment for their condition.

The differences between surgeon and patient perceptions of DTCA found in our study underscore the need to improve the dialogue between patients and surgeons regarding the treatment options for their condition to facilitate true shared decision making.

Some of the important findings of our study include:

- Greater than 98% of surgeon respondents had experience with patients who were exposed to DTCA.
- 74% of surgeon respondents believed that DTCA negatively impacted their relationships with their patients.

- 78% of surgeons believed that their patients were confused or misinformed about the appropriate treatment for their condition based on an advertisement, and 84% of surgeons believed patients who were exposed to DTCA had unrealistic expectations regarding the benefits of a specific type of procedure or implant.

- In contrast, only 18% of patients believed that DTC ads confused them about the appropriate treatment for their condition, and only 37% of patients believed that such ads were misleading in their claims.

- Only 5% of surgeons believed patients were more educated regarding the specific risks and benefits of joint replacement surgery as a result of exposure to DTCA, while the majority of patients surveyed believed that advertisement were helpful in educating them about potential health conditions and their treatment options.

- 52% of surgeons indicated that at times they felt pressured to use a particular brand of implant based on a patient request, and 74% of surgeons believed patients who had been exposed to DTCA at times tried to influence their treatment in a way that could be harmful to them,

- 60% of patients indicated that they had formed an opinion about the type of surgery or specific implant that was appropriate for them *before* consulting with a doctor, and 52% of patients indicated they were more likely to request a specific type of surgery or brand of implant from their surgeon after seeing or hearing an advertisement.

2006 American Orthopaedic Association Annual meeting symposium on DTC Marketing

The use of orthopaedic products requires a high level of clinical judgment, and it is that judgment that needs to be conveyed to the patient. Potential negative consequences of a patient-desired but inappropriate therapy may be significant since a poor outcome cannot be easily corrected. Influence on a surgeon to select an implant with which they lack familiarity may adversely affect the outcome of the surgical procedure.

Efforts to motivate patients to see physicians are most effective when the information conveyed in the DTCA truly informs, sets realistic expectations, and is not confusing to the consumer. Conversely, if a patient requests a specific treatment that the physician does not use or recommend, the patient's interaction with the manufacturer of that specific product has complicated their relationship with that physician. A survey on DTCA of attendees at a 2006 orthopaedic annual meeting was conducted as part of a symposium.[8]

Some of the findings of that survey include:

- DTCA seems to play a substantial role in surgeon and patient decision making in orthopaedics.

- 94% of attendees thought that DTCA would set unrealistic expectations regarding the potential benefits of a particular medical device, drug, or procedure.

- 84% of attendees believed that DTCA of orthopaedic products or procedures changes physicians' practices.

- Surgeons were concerned that a patient would change surgeons if the surgeon was unwilling to provide a specific brand of implant requested by a patient. Only 12% of attendees felt that no patient would switch surgeons while 88% of attendees felt that patients would change surgeons if the surgeon was unwilling to provide a specific brand of implant.

Creation of a National Hip and Knee Implant Registry

In general, surgeons have not reached consensus on the relative merits or performance of a particular medical device over another. Therefore, product specific DTC advertisements related to hip and knee replacement implants are presented out of context when they advocate for one particular device without presenting the range of product options or treatments. Only after collecting sufficient data in a rigorous manner could an evidence-based claim be made that a particular device offers relative benefits over another one in terms of implant longevity or patient function. Long term data collected over twenty years (or longer) may be needed to define optimal product performance and design characteristics. In this regard, the AAOS continues to work with other health care stakeholders in its efforts to develop a national hip and knee registry. The goals of this registry are to improve patient outcomes, decrease revision rates, and allow earlier identification of poorly performing implants. The U.S. joint replacement registry is intended to define best practices and provide an early warning system for hip and knee implants. A similar joint replacement registry in Sweden cut revision surgery rates in half by identifying best surgical practices and best-performing implants in total joint replacements.[20] A ten percent decrease in the number of revision hip and knee arthroplasties in 2005 would have saved the Centers for Medicare and Medicaid Services (CMS) over $100 million that year.

Recommendations

The Internet and the World Wide Web have led to a new generation of technologically savvy and empowered health care consumers who are taking a more active role in finding the best solution for wellness and health care. As surgeons, we applaud efforts by our patients to educate themselves regarding their health conditions and their potential treatment options. However, we believe it is important for patients to evaluate the source and the accuracy of information on which they base their opinions. Sound health care information that is supported by scientific evidence has the potential to enhance the dialogue between physicians and their patients and improve patient satisfaction and the overall quality of care we deliver. However, as our research has shown, biased information contained in direct-to-consumer advertisements promoting specific products

which are not supported by scientific evidence has the potential to cause tremendous harm to the doctor-patient relationship, to create unrealistic expectations among patients, to lead to overutilization of inappropriate and costly unproven medical technologies, which could have dire and expensive public health consequences.

While the marketing of medical devices directly to consumers continues to evolve, we believe that more scientific study needs to be conducted on the effects of medical device marketing on physicians and patients. Furthermore, the different advertising mediums, including newspapers, magazines, the Internet, television, and billboards may necessitate different levels of scrutiny from federal authorities. The AAOS and AAHKS believe that the DTCA of restricted medical products has the potential to create a distorted market, and therefore, we support greater restraint from the medical device industry and greater oversight from the FDA.

The AAOS and AAHKS offer the following specific recommendations to the Committee as it examines the consequences of the DTCA of medical devices.

1. We support ongoing research into the effects of DTCA on the physician-patient relationship, health care utilization and spending, patient safety, and cognitive science.

2. We support disease awareness and help seeking ads which seek to educate patients about their health conditions and the treatment options available to them, rather than product specific advertising. Claims made in product specific advertising related to medical devices are biased, frequently not supported by scientific evidence, and contribute to unrealistic patient expectations and inappropriate requests for specific procedures or implants, which may have grave public health consequences. Furthermore, product specific advertisements have the potential to strain the doctor-patient relationship and lead to inappropriate utilization of specific medical devices or surgical procedures.

3. We support the presentation of a fair balance of risk and benefit information in DTCA of medical devices.

4. We recommend that health care stakeholders should work together to improve the quality and accuracy of information contained in consumer-directed advertisements related to medical devices and surgical procedures.

5. We support increased resources for the FDA, in particular in the area of medical device advertising. AAOS is pleased that the FDA Science Board report has fueled the debate to substantially increase appropriations for the Agency.

6. We support an increased oversight from the FDA Center for Devices and Radiological Health advertising review staff on the DTCA of medical devices.

7. We recommend that the FDA track their reviews of the DTCA of medical devices and should prioritize their reviews.

8. We support a prohibition on DTCA and marketing of restricted medical products to children.

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I appreciate the opportunity to share our views with the Committee on issues related to the DTCA of medical devices, and I look forward to answering any questions you may have.

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[1] Bozic, K.J., Smith, A. R., Hariri. S. et al. The Impact of Direct-to-Consumer Advertising in Orthopaedics. Clin Orthop Relat Res. 2007; May:458:202-19.
[2] R.A. Bell, R.L. Kravitz, M.S. Wilkes. Direct-to-consumer prescription drug advertising, 1989-1998: A content analysis of conditions, targets, inducements, and appeals. J Fam Pract. 2000;49, 329-35.
[3] Food and Drug Administration. Guidance for Industry: Consumer Directed Broadcast Advertisements. Division of Drug Marketing, Advertising and Communications, Aug.1999. Available at: http://www.fda.gov/cder/guidance/1804fnl.htm.
[4] Lyles. A. Direct Marketing of Pharmaceuticals to Consumers. Annual Reviews Public Health 2002; 23:73-91.
[5] Department of Health and Human Services, U.S. Food and Drug Administration. Draft guidance for industry and FDA consumer-directed broadcast advertising of restricted devices. February 10, 2004. Available at http://www.fda.gov/cdrh/comp/guidance/1513.pdf.
[6] Food and Drug Administration. Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms, Division of Drug Marketing, Advertising and Communications, Feb. 2004. Available at http://www.fda.gov/cder/guidance/6019dft.pdf
[7] Food and Drug Administration. Guidance for Industry: Brief summary: Disclosing risk information in consumer-directed print advertisements, Division of Drug Marketing, Advertising and Communications, Feb. 2004 Available at: http://www.fda.gov/cder/guidance/5669dft.pdf
[8] Schaffer, J.L, Bozic, K.J., Dorr, L.D., Miller, D.A., Nepola, J.V. An AOA Symposium: Direct to consumer marketing in orthopaedic surgery: boon or boondoggle. To be published in the J. Bone Joint Surg. Am.2008.
[9] Zachary, W.M., Dalen, J.E., Jackson, T.R. Clinicians' responses to direct-to-consumer advertising of prescription medications. Arch Intern Med; 2003: 163, 1808-12.
[10] Mintzes, B., Barer, M.L., Kravitz, R.L. Bassett, K. et. al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. Can Med Assoc J. 2003; 169, 405-12.
[11]. Bell, R.A., Kravitz, R.L., Wilkes, MS. Direct-to-consumer prescription drug advertising and the public. J Gen Intern Med.1999;14, 651-7.
[12] National Institutes of Health. NIH consensus statement on total knee replacement December 8-10, 2003. J Bone Joint Surg Am. 2004;86:1328-1335.
[13] Kutner, M, Greenberg, E, Jin, Y, Boyle, B, Hsu, Y, Dunleavy, E. Literacy in Everyday Life: Results from the 2003 National Assessment of Adult Literacy. April 2007. US Department of Education, NCES 2007-480.
[14] Donohue JM, Cevasco M. A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med. 2007. Aug 16;357(7):673-81.
[15] U.S. General Accounting Office. Prescription Drugs- FDA Oversight of Direct-to-Consumer Has Limitations. GAO-03-177, Oct. 2002.
[16] Ma, J, Stafford, RS, Cockburn, IM, Finkelstein, SN. A Statistical Analysis of the Magnitude and Composition of Drug Promotion in the United States in 1998. Clin Ther 25(5):1503-17, 2003.
[17] Impact of Direct-to-Consumer Advertising on Prescription Drug Spending. Kaiser Family Foundation. June 2003.
[18] Ibid, GAO-03-177.
[19] U.S. Government Accountability Office. 21st Century Addressing Long-Term Fiscal Challenges Must Include a Re-examination of Mandatory Spending. GAO-06-456T, Feb. 15, 2006.

[20] Malchau, H et al. The Swedish Total Hip Replacement Register.2002. J. Bone Joint Surg. Am., 84:2-20.

The CHAIRMAN. Thank you. We'll move on to Dr. Boden.

Dr. Diamond, please hold your testimony to 5 minutes.

STATEMENT OF WILLIAM E. BODEN, M.D., PROFESSOR OF MEDICINE AND PUBLIC HEALTH, UNIVERSITY OF BUFFALO, BUFFALO, NY

Dr. BODEN. Thank you, Senator. Beg your pardon.

Before we testify we'd like to ask your permission to play a copy of the broadcast advertisement that is the subject of the article that we recently published in the New England Journal of Medicine and which explains the dangers associated with the type of direct-to-consumer advertisements for the restricted medical devices that we are discussing here today.

May we see the DVD?

[Audience watching DVD advertisement.]

Dr. BODEN. Thank you, Mr. Chairman and honored members of the Committee. We appreciate the opportunity to come before you this morning. To express our concerns relating to this direct-to-consumer advertising or DTCA of the intra-coronary stent to the lay public and to healthcare consumers.

This advertisement appeared 10 months ago during the Dallas Cowboys/New York Jets nationally televised Thanksgiving Day NFL game. It was the first direct-to-consumer advertising campaign of a drug eluting coronary stent that was launched by a device manufacturer, that is to say Cordis, Johnson and Johnson. Their initial 60 second advertisement featured in this segment, which was boldly entitled, "The life wide open" on the surface is quite provocative, as we will maintain. We believe that this initial medical advertisement has crossed the line in promoting a particular coronary device to millions of individuals who are unable to discern many of the subtle and complex therapeutic issues that even we cardiac specialists continue to debate.

The distinction between drug and device DTCA is significant. Unlike drugs that merely require a physician office visit and an explicit prescription by a physician or provider than can be then filled by a patient at the pharmacy. A specialized medical device such as the Cypher Stent requires a very sophisticated medical understanding that few individuals in the lay public could realistically expect to gain from such a short 30 to 60 second TV ad campaign.

During a diagnostic coronary angiogram during which we would detect the blockages or narrowings that might result in a potential stent procedure, a cardiac patient may be in significant pain, medicated with sedatives or analgesics, potentially acutely overwhelmed with the recent disclosure of obstructive coronary artery disease. Thus unable to fully comprehend all of the therapeutic implications of which type of stent would be best for him or her in the setting of an impending operative procedure. It seems difficult if not impossible to imagine that a patient would in the above clinical context attempt to challenge the interventional cardiologist's judgment and clinical acumen by calling into question which particular stent type, for example, the Cypher Stent, should be used for that procedure.

It seems equally plausible that an interventional cardiologist would exceed to a patient's request for a particular stent type

based solely on a patient's very limited information derived from a DTCA that touts that one particular stent over another. This makes it very difficult to understand what impact, if any, direct-to-consumer advertising directed at the lay public could in a meaningful way influence Cypher Stent usage at the patient level. The statutory authority for the current regulation of DTCA by the Food and Drug Administration actually goes back 70 years ago to 1938 when the Federal Food, Drug and Cosmetic Act outlined the requirements for pharmaceutical products for which companies sought U.S. marketing approval.

Several years later in 1962, Congress specifically granted the FDA statutory authority to require prescription drug labeling in advertising including direct-to-consumer advertising. In 1969 the Agency issued final regulations governing drug advertising stipulating that advertisements must not be false or misleading, must present a fair balance of information about both the risks and the benefits of using a given drug, must contain facts that are material to the product's advertised uses and must include a brief summary mentioning every risk described in the product's approved labeling. Current Agency regulations differentiate between print and broadcast direct-to-consumer advertising.

In the former print medium all information about associated risks including major side effects, contraindications and precautions contained in the drug's FDA label must be explicitly divulged. By contrast in the broadcast advertisements, only so called major risk information must be stated. But such broadcast ads must direct viewers to other accessible sources containing complete risk information. This distinction reflected a pragmatic recognition of the time limitations, typically 30 to 60 seconds of broadcast ads. By the way in this particular ad that we saw, if you go to the website shown on the ad it provided no explicit safety information when one attempted to elicit that.

About 10 years ago in 1997, the FDA issued a preliminary guidance for industry that re-interpreted FDA regulations without actually changing the regulations. They reiterated that the advertising be non-deceptive and must present a fair balance between information about effectiveness and information about risk, include a thorough major statement conveying all the product's most important risk information in consumer friendly language and must communicate all information relevant to the product's indication including limitations to use in consumer friendly language.

The CHAIRMAN. Mr. Boden? Dr. Boden?

Dr. BODEN. Yes?

The CHAIRMAN. Your time. Could you summarize your statement?

Dr. BODEN. Yes, sir. So in what I would like to actually state then is that there are several recommendations that we would like the Committee to consider.

First, that the FDA should place drugs and devices on the same regulatory footing. DTCA should be required to reflect the evidenced based clinical data that have demonstrated only the proven clinical benefit of the drug or device before being advertised. Unsubstantiated therapeutic claims or expert consensus are not evi-

dentiary and should not constitute an approved basis for advertising to the lay public.

Congress should authorize the FDA to adopt the model used to promote DTCAs used in New Zealand by establishing an advisory panel under the Federal Advisory Committee Act that would vet and discuss all advertising prior to final publication. This could comprise a multidisciplinary Committee with representative membership that would include the drug or device industry, physician specialists and consumer union representatives. The FDA should consider establishing a fund in which a certain percentage of product claim advertising revenue would be tithed and redirected to help seeking ads that promote public health education and heighten public awareness of a particular disease state. This would create a methodology for promoting fair, objective and balanced consumer health education to the lay public devoid of potential commercial bias.

Last, the Committee might consider enacting a ban for the first two years on all DTCA of drugs or devices that have been FDA approved in order to assure that post marketing surveillance and phase four clinical data acquisition have established an appropriate safety record and profile before they are advertised broadly to the public. Thank you very much. Now I'd also like Dr. Diamond to also add some comments please.

[The prepared statement of Dr. Boden follows:]

Direct-to-Consumer-Advertising (DTCA) of Angioplasty and Stents For Chronic Angina:

Public Statement for the Record

Senate Special Committee on Aging

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September 17, 2008

Over 12 million Americans (and hundreds of millions worldwide) suffer from chronic angina pectoris (chest discomfort) due to the progressive "hardening of the arteries process", known as atherosclerosis, that either gradually restricts blood flow to heart muscle causing angina or, in its more malignant expression, abruptly blocks flow to a portion of heart muscle, resulting in a myocardial infarction (MI), or heart attack. Three treatment approaches exist to treat both angina and MI: medical therapy (agents such as aspirin, beta-blockers, statins, and blood pressure-lowering treatments like ACE inhibitors); coronary artery bypass graft (CABG) surgery, or percutaneous coronary intervention (PCI), more commonly known as coronary angioplasty with stents to prop (and keep) open narrowed coronary arteries. PCI is life-saving when used emergently for acute MI; medical therapy for heart attack (often using blood clot-busting drugs known as thrombolytics) is less effective, while CABG surgery acutely is rarely employed and is probably more dangerous in an emergent heart attack situation. Thus, for the treatment of acute MI, PCI has become the accepted and preferred approach to management.

By contrast, about one-half of all patients with atherosclerosis have more chronic forms of angina that are not emergent indications for PCI or CABG surgery. Because PCI and stents can be performed both safely and effectively in heart attack patients and in the larger population of patients with so-called "stable coronary artery disease" who typically manifest chest pain symptoms of angina with exertion, there has been a prevalent belief among both physicians (cardiologists, internists, primary care physicians) and patients (including lay public health consumers without known heart disease) that PCI is equally effective for reducing death, recurrent heart attack and recurrent hospitalizations for chest pain in both heart attack <u>and</u> angina patients.

PCI represents a multi-billion dollar industry that supports significantly both hospital and physician revenues. In a competitive marketplace, stent manufacturers and the device industry now appear poised to bring the marketing and advertising of such interventions into the living rooms of Americans through television-based direct-to-consumer-advertising (DTCA) to the lay public.

Background and History of DTCA

DTCA is generally described as any promotional effort by pharmaceutical companies to present prescription drug information to the general public through the lay media.[1] Such ads, which may appear in newspapers, magazines, non-medical journals, pharmacy brochures, direct mail letters, and on television, radio and Internet websites, usually fall into one of three categories:[2]

1. "Product-claim" ads that include a product's name and a therapeutic claim (typically of benefit) about the product.
2. "Help-seeking" ads that promote public health education and discuss a particular disease or health condition, and advise the consumer to "see your doctor", but do not explicitly mention a product's name.
3. "Reminder" ads that call attention to a product's name but make no reference to the health condition the drug is used to treat.

Of these three categories, U.S. Food and Drug Administration (FDA) has the authority to directly regulate only product-claim ads. The regulations require that therapeutic claims not be "false or misleading". For 70 years, Congress has overseen, through the FDA, the

authority to regulate prescription drug advertising which, at that time, consisted primarily of print advertisements in medical journals directed largely toward physicians. The statutory authority for current regulation of DTCA to the consumer public emanated from congressional legislation in 1938, during which the Federal Food, Drug, and Cosmetic Act (FFDCA) outlined the requirements that pharmaceuticals must meet before they could be approved for marketing in the United States.[3] Section 201 of the Act gives the FDA broad authority to consider drugs "misbranded" if their labeling or advertising is false or misleading in any way. In 1962, Congress added Section 502(n) to the Act in order to give the FDA statutory authority to regulate prescription drug labeling and advertising, including DTCA.[4] In effect, the FDA was charged with regulating pharmaceutical effectiveness in addition to regulating safety. Moreover, responsibility for prescription drug advertising was transferred from the Federal Trade Commission, which still regulates advertising for over-the-counter drugs, medical devices, in addition to hospitals, clinics and physicians) to the FDA. Importantly, in the same section of the amendment, Congress *prohibited* FDA from "issuing any regulations that would require prior approval of the content of any advertisement," presumably because this would violate constitutional First Amendment rights.

In 1969, FDA issued final regulations governing drug advertising at 21 C.F.R § 202/1.[5] Under these regulations, advertisements must meet four basic attributes: 1) they cannot be false or misleading; 2) they must present a "fair balance" of information about the risks and benefits of using the drug; 3) they must contain "facts" that are "material" to the product's advertised uses; and 4) in general, the advertisement's "brief summary" of the drug must include **every** risk from the product's approved labeling.

In 1985, the FDA emphasized that DTCA must meet the same standards as those aimed at medical professionals. Importantly, the agency regulations differentiated between print and broadcast DTCA product-claim ads. In the former, all risk information, including major side effects, contraindications, and precautions that is contained in the drug's FDA label, must be explicitly divulged. In the latter, only "major risk information" must be directly stated, but such broadcast ads must further direct viewers and listeners to other sources from which they can access complete risk information. This regulatory distinction between print and broadcast ads emanates from the more practical consideration that the latter are exquisitely time-limited (typically 30-60 seconds in duration). Thus, broadcast ads would have to include a much shorter but nonetheless lengthy "major statement" of risks, while also making "adequate provision" for viewers to obtain full FDA-prescribing information.[6]

In 1997, the FDA issued a preliminary "Guidance for Industry" that re-interpreted FDA regulations without actually changing any regulations. Reiterating traditional requirements, the Guidance stated that in addition to be non-deceptive, prescription drug advertising must:

- Present a fair balance between information about effectiveness and information about risk.
- Include a thorough, major statement conveying "all of the product's most important risk information in consumer-friendly language".
- Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.[6]

The new interpretation made clear, however, that the "major statement" in radio and TV ads could be far simpler than what had been previously required. "adequate provision" of required information could be achieved by including a very concise summary of risks and related information (often via voice-over), while identifying sources for more complete information (e.g., an 800 number, an Internet website address, either concurrent print ads or information about specific, publicly accessible locations such as pharmacies; plus a statement that all information is available from all physicians and pharmacists.[6] In the wake of the August 1997 policy change, DTCA continued to accelerate, reaching $1.31 billion in 1998, $1.9 billion in 1999, $2.5 billion in 2000 and $2.7 million in 2001.

DTCA of the Cypher® Stent

On November 22, 2007, during the Dallas Cowboys-New York Jets nationally-televised Thanksgiving Day National Football League game, the first direct-to-consumer advertising (DTCA) campaign of a drug-eluting coronary stent was launched by a device manufacturer. Cordis/Johnson & Johnson, Inc. initiated a 60-second advertisement of their sirolimus stent (known as Cypher™) in a featured segment boldly entitled "Life Wide Open". This marked the dawn of a new era in DTCA within the medical industry which, heretofore, has witnessed a virtual explosion in television advertising of branded pharmaceutical agents to the lay public over the past decade. Such an advertisement may have not seemed surprising or out of place to many consumers regularly exposed to a plethora of DTCA initiatives by way of network and cable broadcasts; yet, it marked a

virtually unprecedented transition of this practice from pharmaceuticals to medical devices. On the surface, the provocative "Life Wide Open" advertisement touting the benefits of the Cypher™ drug-eluting stent (DES) seemed no different from similar television ads espousing the virtues of various prescription-brand drugs directed at acute coronary syndromes, arthritis, depression, prostatic enlargement, restless leg syndrome and, of course, erectile dysfunction. In comparison, however, the "Life Wide Open" DTCA campaign raises new, important questions regarding the net societal benefit of medical advertising to the lay public. Even if there is a general benefit to the unfettered transmission of information in a free society with precedent First Amendment protection, has the medical industry crossed the line in promoting this particular device to millions of individuals who are unable to discern many of the subtle and complex therapeutic issues that even specialists continue to debate?

The Distinction of Drug vs. Device DTCA

Unlike drugs that merely require a physician office visit and an explicit prescription by a provider (physician or physician-extender) that can then be filled by the patient at a pharmacy, a specialized medical device such as the Cypher® stent requires a very sophisticated medical understanding that few individuals in the lay public could realistically expect to gain from a DTCA campaign. During a diagnostic coronary angiogram that might result in a potential PCI procedure, a cardiac patient may likely be in significant pain, medicated with sedatives or analgesics, potentially acutely overwhelmed with the recent disclosure of obstructive coronary artery disease and, thus,

unable to comprehend fully all of the therapeutic implications of which type of stent would be best for him or her in the setting of an operative procedure. It seems difficult, if not impossible, to imagine that a patient would, in the above clinical context, attempt to challenge an interventional cardiologist's judgment and clinical acumen by calling into question which particular stent type (bare metal stent or drug-eluting stent [DES] and, in the latter instance, Cypher® versus Taxus®) should be used. Moreover, many hospitals have explicit vendor agreements and volume incentives that may restrict stent inventory to one particular type of DES or, depending on lesional characteristics, limit the choice of DES to one that fits the appropriate coronary anatomic considerations. It seems highly unlikely that an interventional cardiologist would accede to a patient's request for a particular stent type, based solely on the patient's very limited information derived from a DTCA that touts that one particular DES. Accordingly, it is hard to understand what impact, if any, the DTCA campaign directed at the lay public could, in a meaningful way, influence Cypher® stent usage at the patient level.

FDA Regulatory Authority of DTCA

While extant law and FFDCA regulations do not give FDA prior approval authority for prescription drug advertising, the law does give FDA authority to review the accuracy of claims in a prescription drug's promotion.[7] If the FDA feels that an advertisement for a drug that is before the public does not contain the required information or is "false of misleading", it can respond through a variety of enforcement actions. In most cases, the FDA asks the company to withdraw the violative ad. It can

initiate correspondence to the company (known as an "untitled letter" by the agency), which warns that the advertisement violates the FFDCA. Often, the letter states that the ad is "misleading" because it overstates or guarantees the product's effectiveness, expands the population approved for treatment, or minimizes the risks of the product. The letter typically asks that the ad be stopped immediately.

A more stern correspondence that the FDA can initiate is a "Warning Letter" to the company directed at more serious violations. Warning Letters state that, in addition to stopping the violative activity, the company must take corrective steps by disseminating corrective information to the audience of the violative promotional materials such as physicians, pharmacists, and patients. At times, companies may be required to run ads in the same media to correct misleading information or impressions. Usually, companies respond immediately to both "untitled" and "warning" letters, in part, because companies recognize that not only does FDA act as a watchdog to promote fair balance and content in DTCA, but that manufacturers know that the FDA approves all their new products, their manufacturing methods and facilities, and other essential operations such as clinical trials.

Thus, given that pharmaceutical firms invariably accede to FDA requests to alter or halt advertising claims, the FDA possesses an enormous capacity to resolve difficulties to its satisfaction (i.e., the prompt cessation or alteration of a questioned advertising claim or campaign) without proceeding with litigation or a court challenge, even though the FTC has, for decades, been forced to articulate and defend empirically based standards that can withstand scrutiny in the courts, including First Amendment challenges. While the FDA has never had to defend it policies in court, it is likely that the Supreme Court

would probably provide First Amendment protection to DTCA, given its longstanding support for upholding commercial free speech decisions that are pragmatically based.

As noted previously, while the law explicitly prohibits FDA from requiring pre-publication review and approval of ads, most manufacturers voluntarily choose to submit proposed ads to FDA prior to their public release in order to avoid the expense of pulling an already launched ad campaign. Thus, the voluntary pre-review and after-the-fact system of post-publication review by FDA, absent any new legislative change, provides the FDA with statutory authority to impose requirements on the content of advertisements to ensure that ads provide accurate and unbiased information.

Additionally, Congress could investigate (and potentially replicate) the experience in New Zealand, the only other developed nation that permits DTCA of prescription drugs. In that country, all ads making therapeutic claims for advertised products must first be pre-approved by the Association of New Zealand Advertisers, Therapeutic Advertising Pre-Vetting Service, which promotes an industry-based, self-regulatory advertising framework or code of conduct that encourages fair balance of advertising content. Through Congress' encouragement, FDA could establish an advisory panel under the Federal Advisory Committee Act which could either itself recommend standards for prescription drug ads, or encourage industry to develop a new set of standards for self-regulation.

Alternatively, additional regulatory activity by FDA would require new statutory authority, should Congress decide that there is a need for greater enforcement of standards for DTCA. Such new regulatory authority could include an increase compliance and enforcement tools such that Congress could authorize FDA to impose

punitive sanctions against companies that violate the law, an explicit requirement of re-release review of all DTCA before ads are released to the general public, set limits on the timing and placement of ads such that the long-term risk-to-benefit ratio for new prescription drugs could be more completely defined before millions of people are put at risk or, finally, to ban all DTCA to the lay public. As noted, however, such a complete ban would likely trigger court challenges to First Amendment and commercial speech protections. Alternative possibilities might include a time-limited ban of DTCA of 1-2 years after a new drug has been approved in order to collect additional drug/device safety data, or to explicitly require more prominent disclosures in the ads about the safety of prescription drugs, especially the inherent risks of potential safety concerns of new drugs.

Concerns Relating to Advertising Deception

Accordingly, it is hard to understand what impact, if any, the DTCA campaign directed at the lay public could, in a meaningful way, influence Cypher® stent usage at the patient level. Perhaps more concerning is the fact that the "Life Wide Open" television broadcast campaign implicitly promises a better life ("when you open up your heart, you open up your life") without adequately informing the public, as print ads are required to do, about the totality of possible complications and adverse clinical events that may occur. Why does the Cypher® stent patient education brochure detail all potential serious complications whereas the "Life Wide Open" campaign shows only the potential benefits? Does such a DTCA campaign using the Cypher® stent comply with FDA's existing regulatory requirements of "fair balance" or does it fall significantly short

of these stipulations? Can an unsuspecting lay public place sufficient trust in such a broadcast ad campaign to fully understand the significant risks of the Cypher® (or any) stent that are being only minimally addressed in a 60 second ad? Lastly, as FDA requires, why does the cypherusa.com website fail to adequately address important safety concerns or direct patients to a source of educational information that details comprehensively the entire spectrum of complications, risks and adverse events of the Cypher® stent in a full disclosure fashion?

Concluding Comments

We believe that the FDA should perform a critical post-release review the "Life Wide Open" DTCA in accordance with existing regulatory policy to ensure that Section 502 (n) of the FFDCA, updated and modified in 1969 and re-interpreted for broadcast usage in 1997, meets the basic requirements for non-deceptive prescription drug advertising:

- It must present a fair balance between information about effectiveness and information about risk.
- It must include a thorough, major statement conveying "all of the product's most important risk information in consumer-friendly language".
- It must communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.

Additional Recommendations

- FDA should place drugs and devices on the same regulatory footing. DTCA should be required to reflect the evidence-based clinical data that have demonstrated only the proven clinical benefits of the drug or device being advertised. Unsubstantiated therapeutic claims or expert consensus opinion should not constitute an approved basis for DTCA to the lay public.
- Congress should authorize the FDA to adopt the model used to promote DTCA as used in New Zealand by establishing an advisory panel under the Federal Advisory Committee Act that would vet and discuss all DTCA prior to final publication. This could be a multidisciplinary committee with representative membership that would include the drug or device industry, physician specialists, and consumer union representatives. Such a Therapeutic Advertising Pre-Vetting Service would promote a self-regulatory, advertising framework or code of conduct that encourages fair balance of advertising content.
- The FDA could consider establishing a fund in which a certain percentage of "product-claim" advertising revenue would be tithed and re-directed to "help-seeking" ads that promote public health education and heighten public awareness of a particular disease state or health condition (a "see your doctor" that does not explicitly mention a product's name). This would create a methodology for promoting objective, fair, and balanced consumer health education to the lay public devoid of potential commercial bias.
- Consider enacting a ban for the first 2 years on all DTCA of drugs or devices that have been FDA-approved in order to assure that post-marketing surveillance and

Phase IV clinical data acquisition have established an appropriate safety record and profile before they are advertised broadly to the public.

References:

1. Pines WL: a history and perspective on direct-to-consumer promotion. *Food and Drug Law Journal* 1999; 54: 489-518
2. Vogt DU: Direct-to-consumer advertising of prescription drugs. *Congressional Research Service Report for Congress*, Library of Congress, 2005; 1-32.
3. Calfee JE: The leverage principle in FDA regulation information, in Robert Helms, ed., *Competitive Strategies in the Pharmaceutical Ind*ustry, American Enterprise Institute, Washington D.C., 1996; 306-321.
4. Calfee JE: Public policy issues in direct-to-consumer advertising of prescription drugs, American Enterprise Institute, Washington, D.C., 2002; 1-61.
5. Aikin KJ, Swasy JL, Braman AC: Patient and physician attitudes and behaviors associated with direct-to-consumer promotion of prescription drugs: summary of FDA survey research results, final report, *U.S. Department of health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research*, November 19, 2004.
6. Borow W: The American Medical Association explains its about-face on direct-to-consumer advertising, *Medical and Marketing & Media*, 1993; 68-74.
7. Gascoigne D: Direct-to-consumer advertising at the crossroads: a 'direct' hit or 'miss'? *IMS Issues and Insights*, September 23, 2004; 111-123.

Table 1A:

Potential Adverse Events Associated with Coronary Stent Placement

(From page 19; "Patient Information Guide for the Cypher Sirolimus-Eluting Coronary Stent", Cordis Corporation , 2005)

- Allergic reaction
- Aneurysm
- Arrhythmia
- Cardiac tamponade
- Death
- Dissection
- Drug reactions to antiplatelet agents, anticoagulants, or contrast media
- Emboli, distal (tissue, air, or thrombotic emboli)
- Embolization, stent
- Emergency CABG surgery
- Failue to deliver the stent to the intended site
- Fever
- Fistulization
- Hemorrhage
- Hypotension/hypertension
- Incomplete stent apposition
- Infection and pain at the intended site
- Myocardial infarction
- Myocardial ischemia
- Occlusion
- Prolonged angina
- Pseudoaneurysm
- Renal failure

- Re-stenosis of stented segment (greater than 50% obstruction)
- Rupture of native coronary artery or bypass graft
- Stent compression
- Stent migration
- Thrombosis (acute, subacute, late)
- Ventricular fibrillation
- Vessel spasm
- Vessel perforation

Table 1B:

Potential Adverse Events Related to Sirolimus

(Following Prolonged Oral Use)

- Abnormal liver function
- Anemia
- Arthralgias
- Diarrhea
- Hypercholesterolemia
- Hypersensitivity, including analphylactic or anaphylactoid reactions
- Hypertriglyceridemia
- Hypokalemia
- Infections
- Interstitial lung disease
- Leucopenia
- Lymphoma and other malignancies
- Thrombocytopenia

STATEMENT OF GEORGE A. DIAMOND, M.D., F.A.C.C., SENIOR RESEARCH SCIENTIST, EMERITUS, CEDARS SINAI MEDICAL CENTER, LOS ANGELES, CA

Dr. DIAMOND. Mr. Chairman, thank you for inviting me to contribute to these deliberations. I concur completely with the comments of my colleague, Dr. Boden and would simply like to make one additional point.

Direct-to-consumer medical advertising stands at the end of a long chain of regulatory processes by a series of agencies. Each of these agencies has its own relatively narrow aims and none of them communicate very well with one another.

First, the FDA determines the treatment's safety and efficacy. CMS then determines if the treatment is reasonable and necessary. Individual payers then determine that reimbursement is usual and customary. Professional organizations, such as the American College of Cardiology, issue consensus guidelines to the effect the treatment that is useful and effective. Finally the courts decide that treatment is prudent and cautious.

At no point in this chain is there any direct focus on the ultimate goal of healthcare, the provision of clinical benefit. The goal of medicine is not to provide prudent, usual or reasonable treatments. It is to improve longevity or quality of life.

The direct-to-consumer ad serves this higher goal no better than the average political ad serves the ideals of the Democratic process. It simply introduces another myopic link in the chain, consumer opinion. The direct-to-consumer problem is therefore best approached by deconstructing this chain and developing a coordinated, stream lined, regulatory approach designed to serve the dual goals of safety and benefit.

From this perspective the question to be addressed by this Committee is not how direct-to-consumer ads be regulated. But at what point along the stream lined, regulatory chain, in our free market society, do such ads appropriately, effectively serve these goals. My answer, only when two conditions are satisfied.

First, the treatment should target an issue of material, clinical importance. There is little need to regulate ads regarding the latest cold remedy.

Second, the claim should be supported by rigorous, scientific evidence. That would be news we can use, so to speak.

But advertisements are not the only way to get this news. CMS's new Chartered Value Exchange network, Secretary Leavitt's most significant legacy to quality improvement could become the vehicle for transforming policy into practice by translating the various regulatory and clinical findings into information that the public can understand and trust. We will thereby empower them to be informed partners in their healthcare, a worthwhile goal to be sure.

We will know we have succeeded in reaching this goal when direct-to-consumer advertising becomes completely superfluous, if not unseemly. Thank you.

The CHAIRMAN. Thank you, Dr. Diamond. Professor Day.

STATEMENT OF RUTH S. DAY, PH.D., DIRECTOR, MEDICAL COGNITION LABORATORY, SENIOR FELLOW, DUKE AGING CENTER, DURHAM, NC

Dr. DAY. Good morning. My name is Ruth Day. I'm the Director of the Medical Cognition Laboratory at Duke University and Senior Fellow at the Duke Center for the Study of Aging.

I'd like to direct everyone's attention to the screens, as I will be showing slides throughout my testimony.

I'm not here today to argue for or against direct-to-consumer advertising of medical devices. Instead I'm here to report research on how people understand and remember information in these ads. This research was not funded by any medical device company, ad agency, advocacy group or government agency.

The basic question is, how do people understand medical device information? The answer is, with difficulty. There are many possible reasons for this. There's a heavy information load, complex and technical information and so on.

But today I would like to focus on "cognitive accessibility." Cognitive accessibility is the ease of which people can find, understand, remember and use medical device information, and hopefully in a safe and effective manner. We look at a variety of information sources for these ads. Today I'll be focusing just on the ads that air on television and on the internet.

We've been collecting ads for a long time, since the year 2000. Most of our research has been on prescription drugs, but also medical devices.

We use two basic approaches, at least, in this research. First of all we perform cognitive analyses of the ads. We obtain quantitative measures and calculate cognitive accessibility as I'll show you in a bit. Then compare the accessibility of the benefits vs the risks. Then we perform cognitive experiments to test the effects of all of these measures on attention, comprehension, memory, problem solving, decisionmaking, behavior and ultimately health outcomes.

Many cognitive principles underlie this work such as the time spent on certain types of information, repetition, language complexity, speaking speed and other things as well. We study a wide variety of device ads, such as hip replacement, stents, cosmetic procedures and devices for weight reduction. Across all of these, the benefits generally have very high cognitive accessibility, with a lot of time spent on them. There's also repetition of the messages, simple language, normal speaking speed, chunking, put together what goes together, but separate it with pauses on either side for "mental digestion," few other distractions and good locations for the information.

What about the risks? Sometimes they're absent. Quite often they are absent. Other times they're non specific. There will be nonspecific things said such as, "there are potential risks". Risks are sometimes present and when they are, they are generally of lower cognitive accessibility. So all those features we talked about before, are lower in cognitive accessibility for risks relative to the benefits.

Now let's focus on one type of device, joint replacement since it is of special interest to older people. In one ad there's an arthritic

woman and there are no risks presented at all. In another there are some lovely cartoon women and all that's said is, "there are potential risks." One with a home nurse; just "potential risks." Basketball coach; "potential risks." Woman walking across the United States: "potential risks." There's one with a gymnast and potential risks are flushed out. They include a "loosening, dislocation, fracture and wear, any of which could require additional surgery." So only one in six joint replacement ads has any specific risks.

So let's do a cognitive experiment to test the consequences of these presentation practices. We've selected a weight-loss device where a band is put around the upper part of the stomach and can be adjusted to control the flow of food. Participants in our experiment saw the ad. Then we tested their knowledge about the benefits and the risks using multiple tasks.

A very simple thing we do is to ask, what is the name of the medical device? As you can see on the slide, just about everyone knows. When we ask, what is it used for, performance is excellent, 96 percent correct. They know it's for weight loss. That's the indication, what it is used for.

When asked about the contra indications who should not use it, their performance is much worse. They just don't get this information. So the indication is a benefit and performance is excellent, while contra indications are a type of risk and performance is poor.

In a free report task we asked, what were the benefits in the ad? Later we asked, what were the risks in the ad? Here are the results for the benefits vs. the risks. As you can see on the slide, knowledge of benefits was twice as good as risks. Here's the breakdown for the specific benefits and risks. One of the risks is fatality or death and just about no one gets that.

In a recognition task, we basically give one benefit at a time and participants decide whether each it was in the ad or it was not in the ad. Then we do the same thing for risks. Chance now is 50 percent correct, because they're just saying yes or no.

For the benefits, there is very high performance. For the risks, just about chance. People just don't know the risks. We can break this down into those benefits that actually were in the ad, 90 percent correct vs. those that were not in the ad. Can they correctly say no, those are not possible risks? Still very good performance, 70 percent correct.

When we look at the risks, it doesn't matter whether the risks we give are in the ad or not—just about chance performance for all of them. Very different performance for risks relatives to benefits. Why? We can trace it to differences in their cognitive accessibility.

So there is an unfair balance in the presentation of risks vs. benefits, in terms of cognitive accessibility.

Here are some recommendations. We need an evidenced-based approach in developing and reviewing ads. We should have these quantitative measures of cognitive accessibility for the benefits, such as location, speed, competing information and so forth. But we should have it for the risks as well. Then we can get both types of information into fair balance.

Otherwise we will be presenting risk information that may be physically present, but functionally absent. Physically present, but functionally absent. People can't get the risks.

So to conclude, risks can go this way, as shown in this animation—toward the person, but over the head and away. However, there is a way to get risk information into the heads of people. That is to increase its cognitive accessibility.

Thank you.

[The prepared statement of Dr. Day follows:]

Testimony to the U.S. Congress, 9/17/08.
Senate Committee on Aging

Direct-to-Consumer Ads for Medical Devices: What Do People Understand and Remember?

Ruth S. Day[1]
Duke University

Introduction

I am a faculty member at Duke University and Director of the Medical Cognition Laboratory. My expertise is in cognitive science – how people understand, remember, and use information.

I am not here today to argue for or against direct-to-consumer advertising of medical devices. Instead, I am here to report research on how people understand and remember information in DTC ads. This research has not been funded by any medical device company, advertising agency, advocacy group, or government agency.

Basic Question

The basic question is – How do people understand medical device information? The answer is – with difficulty.

There are many possible reasons for this difficulty – for example, there can be a heavy information load, complex and technical information, and so forth.

However our focus today is on "cognitive accessibility."
"Cognitive accessibility" is the ease with which people can find, understand, remember, and use medical device information, and do so in a safe and effective manner (Day, 2006). Cognitive in-accessibility occurs whenever people have trouble with any one or more of these processes.

Research Approach

Research in my lab examines a wide variety of medical device information sources including television, the internet, and hardcopy. DTC occurs in all these environments, but today the focus is on video ads that appear on television and/or the internet.

The basic research approach has three phases, based on our past work with prescription drug ads.

Cognitive Analysis Phase. We obtain quantitative measures about how information is presented, calculate cognitive accessibility scores, and compare the cognitive accessibility of information about benefits vs. risks.

Enhanced Display Phase. We keep the same information, but provide it in more cognitively accessible ways, based on well-established cognitive principles.

Test Phase. We perform cognitive experiments to test the effects of the Original and Enhanced versions on various cognitive processes such as attention, memory, comprehension, problem solving, decision making, behavior, and ultimately health outcomes.

Many cognitive principles underlie this work, including various language properties, chunking of information, location of information, speaking speed, and divided attention, as I'll describe shortly.

[1] Box 90086 / Duke University / Durham, NC 27708-0086 / ruthday@duke.edu / http://www.duke.edu/~ruthday/medcog.html

Cognitive Analyses of Medical Device Ads

We have been collecting television ads for prescription drugs continuously since the year 2000. We are currently comparing features of medical device ads to the hundreds of drug ads already in our database.

We examined ads for a wide variety of medical devices, such as stents, joint replacement, implantable defibrillators, breast implants, and drug-device combinations. Of special interest was the treatment of benefits vs. risks.

Benefits

Considerable time is spent on benefits in the ads and they are generally presented in cognitively accessible ways – the language is relatively simple, spoken at normal or slow speed, with short sentences, helpful pauses, relatively few visual distractions, and/or provided in locations known to facilitate cognitive processing.

Risks

In many ads, no risks are provided at all. In other cases, only nonspecific references to risk are mentioned, e.g., "There are potential risks." When risks are provided, they are generally presented in ways that decrease their cognitive accessibility. For example, the language is complex, without helpful pauses, accompanied by visual distractions, and/or provided in locations known to impede cognitive processing.

Example: Joint Replacement

Of particular interest to older adults are joint replacement devices. We examined six such ads. One had no risks at all, the rest mentioned nonspecific risks, and only one had multiple specific risks.

Insert slides/comments here

Variability

There is more variability across medical device ads than drug ads. For example, in drug ads the benefits are usually provided in both visual and oral form and specific risks are usually given orally, either by voice-over or an on-screen character. In device ads, there is often a strong "testimonial" aspect, relying heavily on visual images of an individual able to do wonderful things after getting/using a medical device; in one case, these images are so strong that no there is no oral expression of the benefits at all.

Cognitive Experiment

To examine how consumers understand and remember information in medical device ads, we conducted a laboratory experiment. People saw an ad for a weight-loss device, then participated in a series of cognitive tasks (only some reported here). This particular ad was selected in part because it contained both specific benefits and risks.

Insert slide/comments here

Basic Information

Nearly everyone knew the name of the device and what it is used for (its indication). Although the ad mentioned who should not use the device (its contraindications), participants knew very little about this information.

Free Report Task

Participants were asked to report both the benefits and risks provided in the ad. Consistent with our research on drug ads, they reported twice as many benefits as risks.

Recognition Task

When asked whether specific benefits and risks were given in the ad, there were dramatic differences in knowledge about these two types of information. For example, when asked about information actually in the ad, benefit performance was nearly perfect, while risk performance was at about chance level.

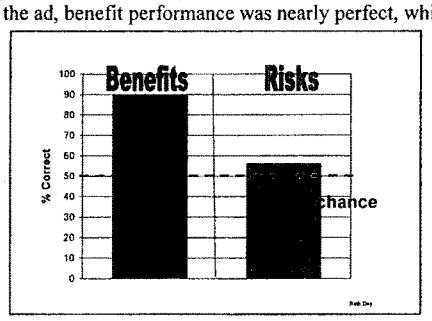


Figure 1 – Percentage correct recognition for benefits vs. risks (for items actually in the ad).

Interpretation

To interpret these results, we examined how benefits and risks were provided in the ad (using cognitive accessibility factors such as those noted above). Overall, the benefits were provided in more cognitively accessible ways than risks. Furthermore, risk presentation violated some well-known, evidence-based principles of human cognition.

Conclusions

Overall, risk information is seriously disadvantaged relative to benefits in medical device ads – the techniques used to present them often render them lower in cognitive accessibility. Although these cognitive accessibility problems are widespread, there are some exceptions – for some factors in some ads. We plan to increase the cognitive accessibility in fictious medical device ads – to determine what information people can understand and remember.

Recommendations

An evidence-based approach is needed to evaluate ads in terms of cognitive accessibility factors such as those described here. Separate analyses of benefits and risks are needed, to ensure that there are no major discrepancies in their cognitive accessibility. Ads with unfavorable cognitive accessibility scores – known to decrease comprehension and memory – can then be modified. Otherwise, risk information will be **physically present, but functionally absent.**

Reference

Day, R.S. (2006) Comprehension of prescription drug information: Overview of a research program. *Proceedings of the American Association for Artificial Intelligence, Argumentation for Consumer Healthcare. aaai.org.*

The CHAIRMAN. Thank you. Ms. Gadhia?

STATEMENT OF AMI GADHIA, POLICY COUNSEL, CONSUMERS UNION, WASHINGTON, DC

Ms. GADHIA. Good morning, Chairman Kohl, Ranking Member Smith and members of the Committee. My name is Ami Gadhia. I'm policy counsel with Consumers Union, the non-profit publisher of Consumer Reports magazine. I'm here today to testify about DTCA for implantable medical devices and the safety and health concerns related thereto.

Consumers Union commends the Committee for holding today's hearing on this critical consumer safety issue. In addition to our testimony today, CU has registered its concerns about this issue through a petition we submitted to FDA in December of 2007. The petition makes the same recommendations that I make today to the Special Committee.

Most people are familiar with DTC ads for prescription drugs. Now DTC ads for implantable medical devices such as knee and hip replacement hardware and heart valves are also appearing on our televisions. Unfortunately injuries and deaths related to medical devices are also manifesting themselves.

In a December 2007 article entitled, "Medical Devices, Problems on the Rise," our publication, Consumer Reports noted that "reports of deaths linked to medical devices are at an all time high with 2,712 fatality reports in 2006, more than double the number in 1997." This article also notes that in September 2007, FDA issued its own report for its Fiscal Year 2006 saying it had seen a 25 percent increase in adverse events linked to medical devices over fiscal year 2005 including 2,830 deaths, over 116,000 injuries and over 96,000 device malfunctions. A number of studies show significant injury including healthcare acquired infections following implant surgeries.

Both healthcare acquired infections and device failure can and do cause death or serious morbidity and expense. These statistics point to the need for regulation of the claims made in and the warning information transmitted through the advertising of the devices. While FDA review and regulation of DTC prescription drug ads are still in their infancy the Agency currently conducts almost no oversight of DTC ads for implantable medical devices. Consumers Union thus strongly urges Congress to require FDA to conduct the same oversight and regulation of DTC ads for implantable medical devices as the Agency is now authorized to do for DTC drug ads and to expand their review of all of these ads.

In June 2006, Consumer Reports published an article in which we noted that "five percent of survey respondents reported getting an infection shortly after surgery, a significantly higher rate than reported in some major studies." The CDC's National Nosocomicomial Infections Surveillance System report clearly shows hip and knee prosthesis surgery to be a serious source of infection. In some of the NNIS reporting hospitals, the infection rate may run as high as 5 percent or more.

The Agency for Healthcare Research and Quality notes that complication of device, implant or graph was the third most common of the principle diagnosis for hospital stays with MRSA infection in

2004. While this category includes skin graphs, devices and implants contribute to the total of 23,500 reported stays with MRSA infection in 2004. A 2007 Health Affairs article stated, more than 600,000 total knee replacements are performed worldwide each year. This number will likely rise because of the aging population and the expanding clinical indications. The surgery carries risks of potentially life threatening complications including anesthesia related problems, wound and joint infections, deep venous thromboses, injury to nerves and blood vessels around the knee and the potential for future surgical revision.

A Wall Street Journal article published April 10, 2007 described the growth of medical device DTC ads. The warnings of side effects are generally non-existence or minimal, as Dr. Day related. Saying such things as "there are potential risks," potential for complications. We found no ads that advised the consumers of the very real possibility of deadly infection or to urge them to seek out surgical facilities with low infection rates. Examples of websites that offer relatively little or no warnings that we could easily see in clicking through the sites are contained within our written testimony.

It is also important that the ads carry a warning of the potential for infection, morbidity and mortality as a result of surgery and implantation because the system of payments between many device companies and surgeons creates financial incentives to conduct the surgery. These same incentives to use various devices may well have the effect of minimizing the warnings and advice cautioning patients about other solutions such as weight loss, pain medication, physical therapy, etc. A 2007 Wall Street Journal health blog posting reported that nationally "more than 40 surgeons or groups each received at least one million dollars in payments" in 2007.

We raise the issue of industry consulting fees. Because it calls into question the objectivity of a physician as a learned intermediary to fully inform patients of the downsides of such surgeries. This potential problem is another reason to require ads to carry robust warnings.

Given these significant concerns we believe that oversight and regulation could improve consumer safety and outcomes. Specifically CU makes the following recommendations.

FDA should be required to mandate that all print and electronic ads including internet ads for implantable devices warn consumers about one, the very real danger of healthcare acquired infections that can and do result from surgery and follow up care.

Two, the expected life span of the device before failure occurs.

CU supports better oversight of medical device ads as we do for drug ads including an FDA review process before the ads are issued. FDA needs more resources for reviewing DTC ads and taking enforcement action when ads are unlawfully misleading, deceptive or unbalanced. Often FDA does not issue a warning letter until months after a deceptive or misleading ad has been widely aired.

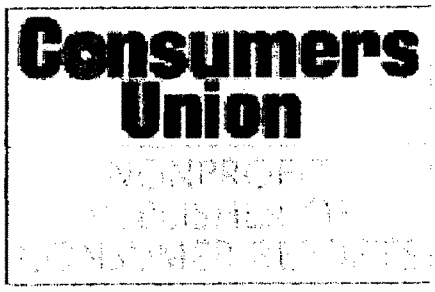
Section 503b of the FDA Amendment Act of 2007 includes stronger authorities for the FDA to require pre-review and specific disclosures to ensure that consumers are warned in DTC ads about potential dangers and side effects. We urge FDA to use these authorities as well as its existing authorities to review device implant advertisements and require that they warn of the specific dangers

of infection. Advise patients to ask questions about infection rates and anti-infection practices at the facility where the implantation will take place.

In conclusion there is no question that many implantable medical devices can restore high quality of life for patients who have been suffering. But we do believe that unintended side effects and deaths can be minimized if the public is better educated about the risks involved and about facilities that are not demonstrating the highest level of anti-infection practices. The law requires that for all DTC ads for prescription drugs the claimed benefits must be accompanied by balanced warnings of the risks of using the drug. The same requirement should be applied to devices.

Thank you.

[The prepared statement of Ms. Gadhia follows:]



Testimony of Ami Gadhia

Concerning the Direct-to-Consumer Advertisements for Implantable Medical Devices

Special Committee on Aging

United States Senate

September 17, 2008

Good morning, Chairman Kohl, Ranking Member Smith, and members of the Committee. My name is Ami Gadhia, and I am Policy Counsel with Consumers Union[1], the non-profit publisher of *Consumer Reports* magazine. I am here today to testify about direct-to-consumer (DTC) advertisements for implantable medical devices and the safety and health concerns related thereto. Consumers Union commends the Committee for holding today's hearing on this critical consumer safety issue.

I. INTRODUCTION

Most people are familiar with direct to consumer, or "DTC" advertisements for prescription drugs. We see them on television almost every day, marketing a broad array of pharmaceuticals. Now, DTC ads for implantable medical devices[2] such as knee and hip replacement hardware and heart valves, are also appearing on our televisions. Unfortunately, injuries and deaths related to medical devices are also manifesting themselves. In a December 2007 article entitled, "Medical devices: Problems on the rise," our publication *Consumer Reports* noted that "reports of deaths linked to medical devices are at an all-time high, with 2,712 fatality reports in 2006, more than double the number in 1997."[3]

The *Consumer Reports* article also notes that in September 2007, "FDA issued its own report for its fiscal year 2006, saying it had seen a 25 percent increase in adverse events linked to medical devices over FY 2005, including 2,830 deaths, 116,086 injuries, and 96,485 device

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[1] Consumers Union (CU) is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and its other publications and websites have a total subscription of approximately 8.6 million. *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] This testimony pertains only to *implantable* medical devices, and not to medical devices such as bandages or contact lenses.

[3] "Medical Devices: Problems on the rise," *Consumer Reports*, December 2007.

malfunctions."[4]

A number of studies show significant injury, including healthcare-acquired infections (HAIs), following implant surgeries. Both HAIs and device failure can and do cause death or serious morbidity and expense.

These injury and death statistics point to the need for regulation of the claims made in, and the warning information transmitted through, the advertising of the devices. While FDA review and regulation of DTC prescription drug advertisements are still in their infancy, the agency currently conducts almost no oversight of DTC advertisements for implantable medical devices. Consumers Union thus strongly urges Congress to require FDA to conduct the same oversight and regulation of DTC ads for implantable medical devices as the agency is now authorized to do for DTC drug ads as well as expand their review of all of these ads. I will explain the scope of the problem with DTC advertising for medical devices, and then I will discuss CU's recommendations to address the problem.

II. DANGERS ASSOCIATED WITH IMPLANTABLE MEDICAL DEVICES

A. Studies show significant injury, morbidity, and mortality following implant surgeries

In June 2006, *Consumer Reports* published an article entitled, "Joint replacement: 1,001 patients tell you what your doctor can't," in which we noted that:

> "Five percent of respondents reported getting an infection shortly after surgery, a significantly higher rate than reported in some major studies."

The aforementioned December 2007 *Consumer Reports* article again makes the point that there are serious consumer issues with the placement and use of some of these devices.

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[4] See footnote 3.

The CDC's National Nosocomial Infections Surveillance (NNIS) System Report clearly shows hip and knee prosthesis surgery to be a serious source of infection, in some cases a high-risk source, and in some of the NNIS reporting hospitals, the infection rate may run as high as 5 percent or more.[5]

Considering deadly Methicillin-resistant *Staphylococcus* aureus (MRSA) infections alone, according to the Agency for Healthcare Research and Quality (AHRQ), 'complication of device, implant or graft' was the third most common of the 'principal diagnoses for hospital stays with MRSA infection in 2004'. While this category includes skin grafts, clearly devices and implants contribute to the total of 23,500 reported 'stays with MRSA infection' for 2004.[6]

Between 1991 and 2001 a study was performed on the 222,684 cases of total knee replacements in California. In the first 90 days of discharge, the study found 1,176 deaths (0.53% rate), 1,586 infections (0.71%), and 914 pulmonary emboli (0.41%). The rates were significantly higher when surgery was performed in low-volume hospitals or on above-average age or patients with other complicating conditions.[7]

A 2007 Health Affairs article (citing a Medline Plus website) stated:

> More than 600,000 total knee replacements (TKRs) are performed worldwide each year; this number will likely rise because of the aging population and the expanding clinical indications. In most cases, TKR can relieve a patient's knee pain, increase the joint's range of motion, and improve quality of life. Nevertheless, the surgery carries risks of potentially life-threatening complications, including anesthesia-related problems, wound and joint infections, deep venous thromboses, injury to nerves and blood vessels around the knee, and the potential for future surgical revision.[8]

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[5] NNIS System Report, data summary from January 1992 through June 2004, issued October 2004. Am J. Infect Control 2004; 32:470-485.

[6] AHRQ, Healthcare Cost and Utilization Project (H-CUP) Statistical Brief #35, July 2007, p. 8.

[7] SooHoo Nelson F; Lieberman Jay R; Ko Clifford Y; Zingmond David , "Factors predicting complication rates following total knee replacement," J Bone Joint Surg Am 2006 Mar; 88(3): 480-485.

[8] Peter Juhn, Audrey Phillips, and Kathy Buto, "Balancing Modern Medical Benefits and Risks," Health Affairs, Vol. 26, No. 3, May/June 2007, p. 648.

Our own review of the ads currently being aired also indicates to us that the target population for these devices is getting younger. For this younger population in particular, the expected lifespan of a device is a critical piece of information.[9]

Another recent study reviewed 2003 nationwide U.S. data to determine the incidences of primary total, partial, and revision hip replacements, and to assess short-term outcomes and factors associated with those outcomes.[10] This study found about a third of a million such hip procedures. The in-hospital mortality rates associated with these three procedures were 0.33%, 3.04%, and 0.84%, respectively. The perioperative complication rates associated with the three procedures were 0.68%, 1.36%, and 1.08% respectively, for deep vein thrombosis or pulmonary embolism; 0.28%, 1.88%, and 1.27% for decubitus ulcer; and 0.05%, 0.06%, and 0.25% for postoperative infection. Rates of readmission for any cause within 90 days ran between 9% for total replacement to 21% for partial. These are very serious operations, infections occur, and consumers need to consider these side effects.[11]

B. Real-life examples from people who suffered deadly infections after knee and hip replacement surgery

For approximately four years, Consumers Union has been working through its Stop Hospital Infections campaign at the state level to enact legislation to require hospitals to publicly report their healthcare acquired infection rates. To date, 24 states have enacted public disclosure and anti-infection laws. These laws vary in their details, but they all are designed to empower consumers and health care providers to call attention to the HAI problem and to take steps to lower the rate of infection.

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[9] http://www.knbc.com/health/13213147/detail.html; http://www.journeytkr.com/commercial.cfm

[10] Zhan Chunliu; Kaczmarek Ronald; Loyo-Berrios Nilsa; Sangl Judith; Bright Roselie A., "Incidence and short-term outcomes of primary and revision hip replacement in the United States," J Bone Joint Surg Am. 2007 Mar; 89(3): 526-33.

[11] See footnote 10.

We are also working at the Federal level in support of legislation to establish a national HAI reporting program (HR 1174) and to call special attention to the growing problem of infections caused by MRSA (HR 4214/S 2278).

Our Stop Hospital Infection campaign has been fueled by the experiences and stories of our readership. We have accumulated approximately 2,000 stories of individuals and family members who have suffered injury and often death due to HAIs. A significant number of these cases occurred following hip and knee transplantation surgery. Many of these stories demonstrate that these HAIs have resulted in terrible pain and suffering, and in too many cases, death.

III. THE NEED FOR FDA REGULATION AND OVERSIGHT OF DTCA FOR IMPLANTABLE MEDICAL DEVICES

A. Examples of Advertisements that Fail to Provide Adequate Warnings of Side Effects, and Especially Fail to Warn of Infection

A Wall Street Journal article published April 10, 2007, entitled "New Medical-Device Ads; Old Concerns, Can a Knee Implant Be Sold This Way. And Should It Be?" describes the growth of medical device direct-to-consumer (DTC) ads. The warnings of side effects are generally non-existent or minimal, saying such things as 'there are potential risks' and 'potential for complications.' We found no advertisement that advised consumers of the very real possibility of deadly infection or to seek out surgical facilities with low infection rates.

For example, while Biomet's website lists a separate risk page and seems unusual in giving a full paragraph to possible complications, their website video advertisement (http://www.biomet.com/patients/oxford.cfm), featuring Mary Lou Retton, fails to mention (as of September 11, 2008) infection or how serious the side effects can be.

Other websites that offered relatively little or no warnings that we could easily see in clicking

through the site are:

-- http://www.genderknee.com

--http://www.aboutstryker.com/files/StrykerCommercial06.wmv

--http://www.journeytkr.com/commercial.cfm

B. Financial Arrangements That May Discourage the Delivery of Side Effect Warnings

It is also important that advertisements carry a warning of the potential for infection, morbidity, and mortality as a result of surgery and implantation, because the system of payments between many device companies and surgeons creates financial incentives to conduct the surgery. These same incentives to use various devices may well have the effect of minimizing warnings and cautioning patients about other solutions (such as weight loss, pain medication, physical therapy, etc.). Our concern is based on recent reports of huge consulting fees to certain surgeons. A 2007 Wall Street Journal Health Blog posting reported that nationally, "more than 40 surgeons or groups each received at least $1 million in payments" in 2007.[12] A 2007 Indianapolis Star article stated that "Federal prosecutors said the industry has a long history of showering gifts on surgeons, making it necessary for companies to fully disclose all of their consulting contracts....the U.S. Attorney's spokesman said the Justice Department is continuing its investigation 'into the practice of certain doctors.'"[13]

We raise the issue of industry "consulting fees," because it calls into question the objectivity of the physician "learned intermediaries" to fully inform patients of the downsides of such surgeries. This potential problem is another reason to require advertisements to carry

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[12] http://blogs.wsj.com/health/2007/10/31/device-makers-post-payments-to-docs-online/?mod=WSJBlog

[13] John Russell, "Docs bristle at suggestion of kickbacks; Feds probe orthopedic surgeons' fees from artificial device makers," Indianapolis Star, November 12, 2007.

warnings.

Other Department of Health and Human Services agencies recognize the importance of fighting HAIs and empowering consumers to understand the dangers of infection and the efforts individual facilities are taking to fight infection. For example, as part of the hospital payment update program, hospitals must report three anti-infection process measures, which are then reported on the CMS website, under "Hospital Compare." The three measures are (1) whether an antibiotic is started during the hour before surgery, (2) whether the correct antibiotic is used, and (3) whether it is discontinued at an appropriate time after surgery. While Consumers Union believes it is most important to report actual infection rates, we do urge consumers to check this website to see how hospitals perform on these process measures. We believe it is important because we have found within a single state, variations among hospitals in good practice of as much as 80 percentage points.

It is also worth pointing out that the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases provides some pamphlet-type information to consumers, such as "Joint Replacement Surgery and You; Information for Multicultural Communities." We do not know how many consumers use or read these materials, but it is interesting to note that on page 8 of this 16-page publication, the first major side effect listed is infection, but the description utterly fails to adequately warn[14] of how serious—how fatal—this problem can be:

> "Joint replacement is usually a success in more than 90 percent of people who have it. When problems do occur, most are treatable. Possible problems include:
>
> > Infection: Areas in the wound or around the new joint may get infected. It may happen while in the hospital or after you go home. It may even occur years later. Minor infections in the wound are usually treated with drugs. Deep infections

[14] "Joint Replacement Surgery and You; Information for Multicultural Communities," U.S. Dept. of Health and Human Services, pg. 8. This omission is particularly distressing in a publication aimed at the minority populations, since MRSA is a particularly serious problem in some of these communities.

may need a second operation to treat the infection or replace the joint."

Clearly, these warnings do not convey the medical horror described by some of our readers in the personal stories we have received through our Stop Hospital Infections Campaign.

IV. RECOMMENDATIONS

A. FDA Expected to Do More to Include Warnings in Advertisements

Given these significant concerns, how can FDA ensure that direct-to-consumer ads for medical devices do not mislead the public? Oversight and regulation, including that which FDA is now empowered to do for prescription drugs DTCAs under Section 503B of the FDAAA, could improve consumer safety and outcomes. Specifically, CU makes the following recommendations:

- FDA should be required to mandate that all print and electronic advertisements, including Internet advertisements, for implantable devices such as knee, hip, heart, valves, cosmetic implants, and other devices, warn consumers about: 1) the very real danger of health care-acquired infections that can and do result from surgery and follow-up care; and 2) the expected life span of the device before failure occurs.
- CU supports better oversight of medical devices ads (as we do for drugs), including an FDA review process before the ads are issued.
- FDA needs more resources for reviewing DTC ads and taking enforcement action when advertisements are unlawfully misleading, deceptive or unbalanced. Often, FDA does not issue a warning letter until months after a deceptive or misleading ad has been widely aired.

- Last week FDA posted a new web page on DTC drug ads which includes a presentation on how consumers can tell a "legal" drug ad from an illegal one and direct actions that people can take to report issues they might have with any ad they see. However, this service only deals with drugs and we believe that implantable devices should get similar attention.

Section 503B of the FDA Amendments Act of 2007 includes stronger authorities for the FDA to require pre-review and specific disclosures to ensure that consumers are warned in DTC advertisements about potential dangers and side effects. We urge FDA to use these authorities, as well as its existing authorities, to review device implant advertisements and require that they warn of the specific dangers of infection, and advise patients to ask questions about infection rates and anti-infection practices at the facility where the implantation will take place.

V. CONCLUSION

There is no question that many implantable medical devices can restore high quality-of-life for patients who have been suffering. CU does not in any way intend to discourage those in pain and facing loss of mobility or other serious problems from seeking out medical advice on implants. But we do believe that unintended side effects, and deaths, can be minimized if the public is better educated about the risks involved and about facilities that are not demonstrating the highest level of anti-infection practices. The law requires that for all DTC ads for prescription drugs, the claimed benefits must be accompanied by balanced warnings of the risks of using the drug. The same requirement should be applied to devices. Requiring information about the danger of infection from surgery in implantable device advertisements will speed the day that America's surgical centers and hospitals address this life-and-death problem.

The CHAIRMAN. Thank you. Senator Salazar, would you like to comment, questions?

OPENING STATEMENT OF SENATOR KEN SALAZAR

Senator SALAZAR. Thank you very much, Chairman Kohl.

I have an opening statement that I will submit for the record.

Senator SALAZAR. I have some questions and comments.

Let me first of all say that this is a very important hearing and I very much appreciate your leadership in bringing this matter to the attention of the Committee and to the attention of the U.S. Senate. A question that I would have for any of you, but Ami, starting with you since you were the one who came up with the recommendations. You essentially are telling us that we ought to have the same kind of oversight and regulation with respect to implantation devices as we now do with the FDA and prescription drugs.

Miss, my question to you is whether or not you think the kind of oversight and regulation that we have from FDA with respect to prescription drugs is working. In all sense what I hear from people as I travel around my state as I did during the month of August where I had 31 hearings on healthcare in 31 counties, is that people think that much of what we are hearing from the pharmaceutical companies with 30 second ads is in fact a huge part of our healthcare problem in America today. So my question is, are we being effective in terms of the kind of regulation that we have with respect to advertising on pharmaceutical drugs? If we're not, why should we simply import that system over to dealing with the kinds of devices that we're dealing with here today?

Ms. GADHIA. You're correct that there's still a lot of work to be done to protect consumers with regards to drug DTC ads. The FDAAA Section 503b does do a lot to try to improve that regulation oversight. It's still relatively new. It's only about a year old.

So I think we're still seeing whether FDA is implementing it or not. As everyone knows they're obviously very strapped for resources. So it's sort of a question of even getting device DTC ads up to the same level.

Senator SALAZAR. Let me ask you this. If, may I compare, I see what we do here in the United States verses what other countries do. Other countries simply prohibit it. I see Dr. Bozic's statement here, it's titled, Marketing or Medicine, Are Direct-to-Consumer Medical Device Ads Playing Doctor?

When you look at the 30 second ads that we see so many of from the pharmaceutical industry, when we look at the devices we're talking about today, why not just adopt the kinds of prohibitions that have been adopted in other countries? Why do we let these 30 second ads essentially be the ones that are playing doctor to a patient?

Ms. GADHIA. I don't disagree with that. It's—

Senator SALAZAR. Then why don't you make that as part of your recommendation instead of just saying apply what is probably not a very workable program with pharmaceuticals to put it into the implantable device industry.

Ms. GADHIA. Just to make sure I understand your question. So why not just prohibit these ads?

Senator SALAZAR. In the way they do in other countries.

Ms. GADHIA. Well, I guess the question is whether the wherewithal exists with the FDA and with the medical device industry being as large as it is in this country whether that exists as a real possibility. The suggestions in my testimony are meant to posit real immediate solutions that we feel could begin to regulate a largely unregulated area.

Senator SALAZAR. On the other hand, are there benefits that come from the kind of advertising that does take place where consumers are made much more informed about the kinds of remedies that might be out there with respect to joint replacements or heart stents or other kinds of things we're talking about here? Other benefits that come from the type of advertising that we see on television today?

Ms. GADHIA. You know I would concur with, I believe it was Dr. Boden, who talked about, I apologize if it was Dr. Diamond, who talked about the confusion and the fact that patients are coming to doctors not knowing a whole lot about these particular devices and what they do. So I think it's questionable whether whatever positive benefits or information are coming from these ads are actually correct.

Senator SALAZAR. Ok. Ms. Day or anybody else want to comment on the question?

Dr. DAY. I do have a comment about potential benefits of these types of ads, since we've been collecting them for over 8 years and been testing them all along. We have seen a growth in what consumers understand about potential side effects for any treatment.

When you ask them, what are possible side effects, they're able to generate more now. So there's more awareness of potential side effects. If you compare our society with the UK, it's a very interesting comparison—similar culture, same language.

I was giving a presentation in the UK recently and afterwards I spoke with colleagues. I asked them, how do you get information about potential side effects for drugs and devices? They said, "side effects?" I said, "well does your physician tell you?" They said, "well, it doesn't come up." That society is less aware that there are always potential side effects with treatments such as drugs and devices, as well as potential benefits. So I—

Senator SALAZAR. Ruth, would you concur with Ami's recommendations in terms of additional FDA resources to regulate as well as regulation extended?

Dr. DAY. Yes. I know some of what goes on in the DDMAC group, that's the Division of Drug Marketing Advertising and Communication. They do a lot of very good work. They are responsible not only for the drug ads we're talking about now, but all the promotional materials, industry websites, the print ads and the promotional materials that go to the physicians. If you look at the total number of pieces of promotional material they're responsible for and divide by the number of staff people who review—I think it's about 25 people.

Senator SALAZAR. So you'd say they have a good program, but they're just very understaffed?

Dr. DAY. Absolutely. I would like to see medical devices come up as Ami Gadhia also said, to at least that standard as well.

Senator SALAZAR. Right.

Dr. DAY. Then consider going beyond that level.

Senator SALAZAR. My time is up. I thank you, Chairman Kohl.

The CHAIRMAN. Thank you very much, Senator Salazar. I just want to follow up, maybe to some conclusion among all five of you. Would you all agree that we need to do a much better job of regulating this advertising, DTC advertising in this area?

Anybody disagree on that?

Dr. DAY. No.

The CHAIRMAN. Do you all see it as a very important issue if we're going to continue to advertise these devices and even increase the advertising on these devices that regulation not only should occur, but must occur? Anybody disagree?

Dr. DAY. No.

Dr. BOZIC. Not at all.

The CHAIRMAN. We thank you so much. Does anybody want to make a comment before we go on to the next panel?

Dr. DIAMOND. Well if I could just add one more statement with respect to the last comment you made. In the end we have to do more than just regulate. We have to link the claims to the evidence.

We eventually have to link the evidence to reimbursement. Because there needs to be an incentive chain throughout the entire process that encourages the right behavior.

Dr. BOZIC. I'd just like to add as we've discussed, I think there's an important distinction between help seeking or disease awareness advertisements which can have some positive health effects, from product specific ads. I do believe that increased resources for the FDA could lead to increased oversight and therefore allow us to have some of this fair balance that we're trying to achieve that we're clearly not achieving under the current system.

Dr. BODEN. I'd just add also that if we could perhaps model a system after what New Zealand has undertaken, a therapeutic, advertising preventing service, that might include multidisciplinary representatives of physicians, specialists, consumer advocates and other regulatory agencies. I think that this might help to go a long way toward ensuring that the content and balance is fair and appropriate for what consumers can expect to understand.

Thank you.

Senator SALAZAR. Mr. Chairman, may I ask one more question?

The CHAIRMAN. Certainly. Go ahead.

Senator SALAZAR. Would any members of the panel take the position that we ought to try to ban these kinds of ads in the way that other industrialized nations have done so? I'm not sure we could do it under the First Amendment. But would any of you take the position that we ought to follow the same pathway that other industrialized nations have taken to ban these kinds of ads?

Dr. BODEN. Senator, I think most of us would probably prefer such a ban, but I think that this might trigger court challenges, you know the First Amendment and commercial speech protections. So I think if there was a way to navigate that, you know it would be, I think, worthy of consideration.

Senator SALAZAR. Ok. Do the rest of you agree with Mr. Boden's comment?

Dr. DAY. I would just like to comment that I do not believe that they have been "banned" in other countries. They have not been approved. It is allowed in New Zealand. Other countries are considering it. There's a lot of talk in the UK that it might happen, or it might not. They go back and forth on this. But I don't think that the countries have actively banned the ads. They just have not approved direct-to-consumer advertising.

Senator SALAZAR. Ok. Thank you very much.

The CHAIRMAN. We thank you so much for being here today. Your testimony has been very useful. Thanks for being here.

So we've moved off to the second panel. Second panel is Dr. Daniel Schultz. He's the Director of the FDA Center for Devices and Radiological Health. That is the office responsible for among other things, the regulation of direct-to-consumer advertisements for restricted medical devices.

So Dr. Schultz, what have you got to tell us this morning?

STATEMENT OF DR. DANIEL SCHULTZ, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD & DRUG ADMINISTRATION, WASHINGTON DC

Dr. SCHULTZ. Mr. Chairman, members of the Committee, my name is Dan Schultz. I'm Director of the Center for Devices and Radiological Health at the Food and Drug Administration. Thank you for the opportunity to discuss today the Agency's role in oversight in direct-to-consumer advertising in promotion of medical devices.

I will discuss how FDA regulates the promotion in advertising medical devices. Clarify some important differences from regulation of drug advertising and promotion. I will also review the Agency's enforcement actions, outreach and compliance activities in these areas.

Under the Federal Food, Drug and Cosmetic Act, FDA has regulatory authority over the labeling of all medical devices. The Federal Trade Commission regulates the advertising of medical devices with the exception of restricted devices. A restricted device is one for which the Agency has issued a regulation or otherwise imposed requirements restricting the sale, distribution or use of a device if such restrictions are necessary for its safe and effective use. FDA therefore regulates the advertising of restricted medical devices and FTC, the advertising of non-restrictive medical devices.

Sections 502Q and R of the Act provide that a restricted device is misbranded if its advertising is false or misleading and in particular, does not contain a brief statement of the devices intended use, relevant warnings, precautions, side effects and contra-indications, excuse me. FDA has issued two draft guidances pertaining to advertising of restricted devices. One entitled Draft Guidance for Industry in FDA Consumer Direct to Broadcast Advertising of Restricted Devices describes an approach for companies in developing advertisements that contain a brief statement of intended uses and relevant warnings, precautions, side effects and contraindications.

The second, entitled, Help Seeking and Other Disease Awareness Communications Buyer on Behalf of Drug and Device Firms assists the drug and device industries in developing such communications. Generally help seeking and other disease awareness communica-

tions do not constitute labeling or advertising and so are not regulated by FDA.

Some of the distinctions. Generally speaking there is no statutory requirement that restricted device or drug advertisements be submitted to FDA for review prior to dissemination or broadcast. The main difference between drug and device promotion occurs at the time of dissemination or broadcast. Medical device companies are not required to submit FDA copies of promotional materials at the time of dissemination. Pharmaceutical companies on the other hand, are required to submit copies of their promotional materials for prescription drug products at the time of initial dissemination.

FDA's drug advertising regulations contain certain specific requirements regarding the content of prescription drug advertisements. For example, drug advertisements may not include false or misleading information or omit material facts and must present a fair balance between benefit and risk. Device regulations do not contain specific requirements regarding the content of advertisements for restricted medical devices. So regulation comes directly from Sections 502Q and R of the Act mentioned earlier.

CDRH regulates restricted device advertisements directed to consumers and physicians, specifically CDRH regulates product claim and promotional reminder ads, product claim ads include the name of the product, its indications for use or make a claim or representation about a specific medical device. Promotional reminder ads may disclose the name of the medical device, descriptive information or price information. But do not provide indications for use or make any claims or representations. As I previously mentioned help seeking and other disease awareness ads are not generally regulated.

CDRH's Office of Compliance in conjunction with support with the rest of the Center is responsible for the surveillance of advertisements for restricted devices as well as promotional materials for all medical devices. The Office of Compliance staff reviewed trade complaints about promotion from competitors, health care professionals and consumers as well as promotional activities in the exhibit halls of scientific and promotional meetings. I just parenthetically would like to say that we do get a lot of valuable information from competitive companies. That's actually one of our best sources.

As well we do send a number of our medical officers and other people around the Center, not just our compliance people to scientific meetings. They're very helpful as well in getting us useful information. Some of which we've actually used to take enforcement actions.

We seek to increase voluntary compliance by industry through educational programs. These include outreach programs intended to improve industry's understanding of the statutory requirements for medical device promotion, website postings and warning letters which provide examples of violations the Agency has acted against and helps industry understand what types of promotion are unacceptable. Guidances to help industry understand FDA's current thinking, how to comply with the Act. In addition in 2005, FDA held a public hearing on DTC promotion to gather input on DTC promotion of regulated medical products. FDA is using information

from that meeting to help guide its policy on the regulation of DTC promotion.

Last year CDRH undertook a major enforcement initiative in the area of off label promotion of medical devices directed to healthcare professionals. In 2007, CDRH met with 20 manufacturers of biliary stents to discuss increased off label promotion for vascular applications. At that meeting CDRH identified several instances in which companies were promoting biliary stent products for uses beyond those cleared by the Agency.

CDRH requested, I think strongly requested, that firms review their device's labeling to ensure it was consistent with cleared indications for use, to stop promoting biliary stents at vascular meetings, to inform their customers of the risks of serious adverse events when biliary stents are used off label and to conduct appropriate clinical trials in support of PMA applications for the specific vascular indication. CDRH worked with the companies to ensure that their corrective actions were fully implemented. Our Office of Compliance continued to monitor companies and assure continued compliance.

The Agency has issued untitled and warning letters to companies for violated broadcasting DTC advertising and promotional labeling. Other enforcement tools that are available to address misbranded or adulterated devices include seizures, injunctions, civil money penalties and referrals for criminal investigation or prosecution. The Agency will maintain vigilance in this area and continue enforcement practices necessary to address the unique issues and challenges presented by consumer directed advertising of restricted medical devices and to target violations with the greatest public health impact. That is, maintain a risk based approach.

Thank you.

[The prepared statement of Dr. Schultz follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DANIEL SCHULTZ, M.D., DIRECTOR
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION
U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

HEARING ON

MARKETING OR MEDICINE:
ARE DIRECT-TO-CONSUMER MEDICAL DEVICE ADS PLAYING DOCTOR?

SEPTEMBER 17, 2008

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Daniel Schultz, M.D., Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the Agency's role and experience in oversight of direct-to-consumer (DTC) advertising of medical devices. My testimony will review how FDA regulates the post-clearance and post-approval promotion and advertising of medical devices, including consumer-directed promotion and advertising, and clarify some important differences between the regulation of drug advertising and medical device advertising. I also will review the Agency's enforcement actions, outreach, and other compliance activities.

Part of FDA's mission to protect the public health is to help ensure that information about medical devices is not false or misleading. This is accomplished through surveillance, enforcement, and education by the Office of Compliance within CDRH in an effort to ensure proper communication of labeling and promotional information to both health care professionals and consumers.

Helping all Americans make better-informed decisions concerning their health care is a priority of the Agency. Opinion surveys conducted by FDA's Center for Drug Evaluation and Research demonstrate that DTC advertising can encourage consumers to seek information from their physician or pharmacist about an illness, condition, or medical product.

STATUTORY AND REGULATORY AUTHORITY

FDA regulates the manufacture, sale, and distribution of medical devices in the United States under authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Medical devices are assigned to one of three regulatory classes based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of the device. Devices posing the lowest risk, such as elastic bandages, are placed in Class I. Class I devices are subject to the "general controls" applicable to all devices. Class II devices, which pose incrementally greater risk and for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, are subject to "special controls" in addition to general controls. Special controls may include labeling requirements, performance standards, post-market surveillance studies, or other controls the Agency deems necessary to provide reasonable assurance of the safety and effectiveness of the device. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and generally are subject to premarket approval (PMA), which means that an application must be submitted to and approved by FDA before the device may be legally marketed. PMA applications must contain information that provides a reasonable assurance of the safety and effectiveness of the device for its intended use and generally include pre-clinical testing and clinical study data.

Under the FD&C Act, FDA has regulatory authority over the labeling of all medical devices. However, FDA's regulation of medical device advertising is limited to a subset of medical devices. The Federal Trade Commission (FTC) regulates the advertising, as

opposed to the labeling, of most medical devices under sections 12-15 of the Federal Trade Commission Act, which prohibit false or misleading advertising of certain products that FDA regulates. (Title 15, United States Code [U.S.C.] section 52-55). Sections 502(q) and 502(r) of the FD&C Act authorize FDA to regulate the advertising of certain devices, which are known as restricted devices (discussed below). Section 502(r) also states that restricted devices are not subject to sections 12-15 of the Federal Trade Commission Act. Thus, FDA regulates the advertising of restricted medical devices while the FTC regulates the advertising of non-restricted devices.

Medical devices may become restricted in one of three ways. (Prescription devices may or may not be restricted devices. See sections 502(f) and 520(e) of the FD&C Act. 21 U.S.C. 352(f) and 360j(e)). Under section 520(e) of the FD&C Act, FDA may by regulation restrict a device to sale, distribution or use only upon the authorization of a practitioner licensed by law to administer or use such device, or upon other conditions that FDA prescribes in the regulation, if FDA determines that there cannot otherwise be reasonable assurance of the device's safety and effectiveness (21 U.S.C. 360j(e)). Alternatively, under section 515(d)(1)(B)(ii) of the FD&C Act, FDA may require, as a condition of approval of a Class III device, that its sale and distribution be restricted, but only to the extent that the sale and distribution of the device may be restricted by a regulation promulgated under section 520(e) of the FD&C Act (21 U.S.C. 360e(d)(1)(B)(ii)). Finally, under section 514(a)(2)(B)(v) of the FD&C Act, FDA may establish, as part of a performance standard promulgated in accordance with section 514(b) of the Act, requirements that the sale and distribution of a device be restricted, but

only to the extent that the sale and distribution of the device may be restricted by a regulation promulgated under section 520(e) of the FD&C Act (21 U.S.C. 360d(a)(2)(B)(v)). Most Class III premarket approval devices have been restricted as a condition of approval, in accordance with section 515(d)(1)(B)(ii) and a few Class I and II devices are restricted by regulation (e.g., hearing aids), in accordance with section 520(e).

Sections 502(q) and 502(r) of the FD&C Act provide the Agency with authority to regulate restricted device advertisements. These sections of the FD&C Act impose specific requirements on the advertising of restricted devices. Section 502(q) of the FD&C Act provides that a restricted device is misbranded if its advertising is false or misleading in any particular. Section 201(n) of the Act provides that, in determining whether advertising is misleading, there shall be taken into account not only representations made or suggested in the advertising, but also the extent to which the advertising fails to reveal material facts regarding the representations made or the consequences that may result from use of the device under its labeled, advertised, or usual conditions of use.

Section 502(r) of the FD&C Act provides that a restricted device is misbranded if any of the advertising pertaining to the device does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects and contraindications. However, the 502(r) advertising requirements do not apply to any printed matter that FDA determines to be labeling under section 201(m) of the FD&C Act. That section defines

labeling as all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article. Neither the restricted device advertising provisions nor any other provision of the FD&C Act addresses issues of product price or medical device coverage by insurance companies.

GUIDANCES FOR INDUSTRY

In 2004, FDA issued two draft guidances pertaining to advertising of restricted devices. One, issued in February 2004, was entitled, "Draft Guidance for Industry and FDA: Consumer-Directed Broadcast Advertising of Restricted Devices." This draft guidance is intended to assist manufacturers, packers, and distributors of medical devices who are interested in advertising their restricted devices directly to consumers through broadcast media, such as television, radio, or telephone communication systems. The draft guidance describes an approach for companies to meet the statutory requirement in section 502(r) that these advertisements contain a brief statement of the intended uses of the device and the relevant warnings, precautions, side effects, and contraindications (21 U.S.C. 352(r)(2)). In the draft guidance, FDA recommends ensuring that audiences exposed to restricted device advertisements on television and radio have convenient access to the labeling of the advertised restricted device. The proposed approach recommends reference in the broadcast ad to different sources consumers could use to obtain more detailed labeling information: a toll-free telephone number, a Web site address, a concurrently running print advertisement, and their health care professional.

The draft guidance can be found on the FDA Web site at:

http://www.fda.gov/cdrh/comp/guidance/1513.html.

Also in 2004, FDA issued a draft guidance entitled, "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (January 2004), which covers both drugs and medical devices. This draft guidance is intended to assist industry regarding "help-seeking" and other disease awareness communications, including a description of the specific characteristics of communications that fall into this category. Disease awareness communications are communications disseminated to health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or medical device or make any representation or suggestion concerning a particular drug or medical device. Help-seeking communications are disease awareness communications directed at consumers. Generally, help-seeking and other disease awareness communications do not constitute labeling or advertising, and therefore are not subject to regulation by FDA. The Agency believes that such communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide, appropriate treatment. The draft guidance can be found on the FDA Web site at:

http://www.fda.gov/cder/guidance/6019dft.htm.

DISTINCTIONS FROM REGULATION OF DTC DRUG ADVERTISING

There is no statutory requirement that restricted device advertisements be submitted to FDA for review prior to dissemination or broadcast. Similarly, with only rare exceptions (primarily for drug products receiving accelerated approval), there is no statutory requirement that prescription drug advertisements be submitted to FDA for review prior to dissemination or broadcast.

The main difference occurs at the time of dissemination or broadcast. Medical device companies are not required to submit to FDA copies of promotional materials for medical devices, including broadcast advertisements, at the time of dissemination. By contrast, pharmaceutical companies are required to submit to FDA copies of promotional materials for prescription drug products at the time of initial dissemination, by submission of a Form 2253.

FDA's drug advertising regulations provide that prescription drug advertisements cannot be false or misleading or omit material facts, and must present a fair balance between benefit and risk information. Further, for print advertisements, the regulations specify that a brief summary of all the risks addressed in the product's approved labeling also must be disclosed. For broadcast advertisements, the drug regulations require ads to disclose the most significant risks – the most serious and most common – that appear in the labeling. The regulations further require that broadcast advertisements either contain a brief summary of all necessary information related to risk from the labeling or make adequate provision for dissemination of the product's FDA-approved labeling in connection with the ad.

By contrast, FDA's device regulations do not contain specific requirements regarding the content of advertisements for restricted medical devices. Regulation of restricted device advertising thus stems directly from the statute, sections 502(q) and (r) discussed earlier, under which a restricted device is misbranded if its advertising is false or misleading in any particular or does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects and contraindications. In addition, the February 2004 draft guidance is meant to assist companies to achieve compliance with these statutory requirements.

PROMOTIONAL MATERIAL AND TYPES OF ADVERTISING

For restricted devices, CDRH regulates advertisements in addition to the promotional labeling that is disseminated by or on behalf of the medical device's manufacturer, packer or distributor. This includes materials that companies disseminate or place for publication that are directed to consumers and physicians, such as ads printed in magazines, journals and newspapers, ads broadcast over television, radio and telephone, brochures, and detailing pieces. The majority of the materials produced are intended for promotion to health care professionals, such as detail aids used by manufacturer representatives, convention displays, file cards, booklets, and videotapes, which are distinct from advertising directed toward consumers.

Of the three different types of advertising that companies use to communicate with consumer, CDRH regulates two of them, "product-claim" and "promotional reminder"

ads. The third type, "help-seeking" and other disease awareness ads, are not generally regulated by FDA, as described in the 2004 draft guidance and discussed earlier.

"Product-claim" ads are those ads which generally include both the name of a product and its indications for use, or make a claim or representation about a medical device. "Promotional reminder" ads may disclose the name of the medical device and certain specific descriptive information or price information, but they do not give the device's indications for use or make any claims or representations about the device.

OVERSIGHT

CDRH's Office of Compliance (OC) is responsible for the surveillance and enforcement of violations contained in the promotional materials of all medical device companies. OC staff review trade complaints about promotion from competitors, health care professionals, and consumers. OC also reviews promotional activities in the commercial exhibit halls of scientific meetings and promotional meetings. Trade complaints are the primary source from which CDRH receives information regarding promotional violations by medical device companies. OC, however, does not track the number of trade complaints received. In rare instances, companies send proposed new DTC broadcast concepts to OC for review and comment in advance of use, although companies are under no statutory obligation to submit their concepts or follow OC's advice. Generally, though, OC does not see final broadcast ads before airing on TV or radio. OC's involvement is mainly post hoc, once the materials have appeared in the public domain.

Educational Programs for Industry

FDA seeks to increase voluntary compliance by industry through educational programs. These programs include:

Outreach Programs: CDRH staff participate in many panel discussions and presentations for groups including industry, law firms, consultants to industry, and marketing and advertising agencies. These programs are intended to increase the understanding of these groups concerning the statutory requirements relating to promotion of medical devices so industry can better comply with these requirements.

Web site Postings: CDRH posts on its Web site all Warning Letters relating to violations involving the promotion of medical devices. These letters serve as useful examples of violations that the Agency has acted against and help industry understand what types of promotion are unacceptable.

Guidances: FDA has published guidances in areas for which industry seeks clarification. Guidances help industry understand FDA's current thinking and recommend how to comply with the FD&C Act.

Public Hearing on DTC Promotion: On November 1-2, 2005, FDA held a public hearing to provide an opportunity for broad public participation and comment on DTC promotion of regulated medical products, including prescription drugs for humans and animals, vaccines, blood products, and medical devices. FDA held this hearing because it believes the Agency, the industry, and other members of the public that have experience with DTC

promotion need to understand what regulatory issues may need to be addressed. FDA was interested particularly in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caretakers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians), managed care organizations, and insurers, as well as the regulated industry. FDA obtained valuable information from its stakeholders at this public meeting and in comments submitted to the docket for the meeting. FDA is using this information to help guide its policy on the regulation of DTC promotion.

ENFORCEMENT RELATED TO PROMOTION AND ADVERTISING OF MEDICAL DEVICES

CDRH's surveillance and enforcement activities cover promotion and advertising directed at both consumers and health care providers. For example, last year, CDRH initiated a major enforcement initiative in the area of off-label promotion of medical devices directed to health care professionals. On March 12, 2007, CDRH met with twenty different manufacturers of biliary (pertaining to bile duct or gallbladder) stents to discuss off-label promotion and use of biliary stents in vascular applications. When indicated for use in treatment of malignant biliary obstruction, biliary stents have been cleared by FDA as Class II devices, through review of premarket notification (510(k)) submissions containing in-vitro bench testing. In contrast, vascular stents have been reviewed and approved as Class III devices, following submission of PMA applications containing additional pre-clinical testing and clinical study data. At the March 12 meeting with biliary stent manufacturers, CDRH identified several instances where we believed

companies were promoting their biliary stent products for uses beyond those cleared by the Agency in the firms' 510(k) submissions.

CDRH requested that firms review their devices' labeling, including all promotional labeling contained on their Web sites, to ensure they were consistent with the indications for use that were cleared in the firms' 510(k) submissions. CDRH also requested that firms stop promoting biliary stents at vascular meetings. CDRH asked that firms inform their customers of the risk of serious adverse events when biliary stents are used off-label in the peripheral vasculature. CDRH also requested that the firms conduct appropriate clinical trials to create accurate and adequate labeling and instructions for use in the peripheral vasculature in support of a PMA application. For several months after the meeting, CDRH worked with companies to ensure that they fully implemented corrective actions in an effort to achieve compliance with the law. Ultimately, all companies involved in the meeting followed CDRH's requested actions. Since the meeting, several companies have initiated clinical trials regarding the use of biliary stents in the vasculature in an effort to obtain PMA approval and appropriate labeling for this intended use of these devices. OC confirms the continued compliance of the companies that were involved in the meeting through periodic monitoring and review of their promotional materials for their biliary stent products.

The prevalence of DTC advertising for restricted medical devices is a fraction of that for drugs, but is increasing. OC performs targeted surveillance and investigation of DTC advertisements for restricted devices and promotional labeling for all devices. Examples

include biofeedback devices, ultrasound devices used in general imaging, cardiac, and intraoperative applications and surgical instrument devices used to cut cardiac tissue. Enforcement tools that are available to address misbranded or adulterated devices include the issuance of regulatory correspondence such as untitled letters and Warning Letters, as well as enforcement actions including seizures, injunctions, civil money penalties, and referrals for criminal investigation or prosecution. Untitled letters cite violations that do not meet the threshold of regulatory significance for a Warning Letter. Warning Letters are issued for violations of regulatory significance that, if not promptly and adequately corrected, could lead to enforcement actions without further notice.

The Agency has issued untitled letters and Warning Letters to companies for broadcasting and disseminating DTC advertising and promotional labeling that violate the FD&C Act. FDA's enforcement actions request that companies stop using the violative materials. In some cases, the Agency asks companies to send corrective letters to correct product misimpressions created by false or misleading materials. FDA attempts to target its resources at the violations with the greatest public health impact.

CONCLUSION

FDA is committed to ensuring that medical device promotion and advertising, including DTC advertising, is truthful and not misleading, that it helps consumers make better informed choices about their health and health care, and that it helps prevent potential misconceptions about benefits and risks of the advertised treatment.

Proponents of DTC promotion of medical products argue that it has educational value and will improve the physician-patient relationship, increase patient compliance with therapy and recommended physician visits, and generally satisfy consumer interest in obtaining desired medical product information. Opponents contend that consumers do not have the expertise to evaluate accurately and comprehend such advertising, that physicians will feel pressure to recommend treatment that is not needed, and that DTC promotion will damage the physician-patient relationship and increase the price of medical products. FDA believes that, if done properly, medical device advertising can provide consumers with important information about medical devices and new indications for existing medical devices, as well as information about symptoms of treatable illnesses and other conditions. Done properly, medical device advertising can assist consumers in taking a proactive role in improving their health. However, to be of value, these advertisements must not be false or misleading.

As a result, FDA will continue to monitor DTC advertising to help ensure that promotional activity is truthful and not misleading. Through these efforts, the Agency will maintain vigilance in this area and continue enforcement practices necessary to address the unique issues and challenges presented by consumer-directed advertising of restricted medical devices and to target violations with the greatest public health impact.

This concludes my remarks, Mr. Chairman. I will be glad to answer any questions you may have.

The CHAIRMAN. Thank you, Dr. Schultz. Dr. Schultz, in your opinion is there any reason why the regulation in the oversight of medical devices by the FDA shouldn't be at the same level as it is for pharmaceuticals?

Dr. SCHULTZ. Mr. Chairman, I think that in terms of the level, I think that the question is really, you know, is it important, yes, absolutely. The question is how do we go about it? I think one of the questions that was asked earlier and one that sort of resonates with me is, how can I use the resources that I have and that you've provided to us in a most effective way to ensure the public health?

Obviously we have a number of other priorities including import safety, product surveillance, good manufacturing, making sure that we have a review process that gets life saving devices to the marketplace in a reasonable timeframe. So the question to me is not is this important? The question is where do I put it in terms of priority? How can I best achieve the goals that we all have?

The CHAIRMAN. Well, I appreciate that. I think what you're saying is your not disregarding the importance of it.

Dr. SCHULTZ. Correct.

The CHAIRMAN. You're suggesting the argument could easily be made that it's just as important to regulate medical devices as it to regulate and oversee pharmaceuticals. But you do not have the kind of resources to enable you to do that. Is that what you're saying?

Dr. SCHULTZ. That, well, that's part of what I'm saying. Yes, that's correct. The other—

The CHAIRMAN. It would not be right—

Dr. SCHULTZ. Alright. Sorry.

The CHAIRMAN. Correct, or fair for anybody in your opinion to make the argument that medical device regulation and oversight is any less important than oversight and regulation of pharmaceuticals in our society.

Dr. SCHULTZ. I'm a surgeon and I'm a device guy. So absolutely not. I think medical devices are as important as any other medical product.

The CHAIRMAN. In terms of the need for oversight, I'm saying.

Dr. SCHULTZ. Well, I think, yeah. I mean, I think that they need to be regulated appropriately for the types of devices that they are. Again, you know, one of the challenges that we—

The CHAIRMAN. Do you think that's important in our society?

Dr. SCHULTZ. Excuse me?

The CHAIRMAN. Do you think that that regulation and oversight of medical devices is an important thing to be accomplished in our society today?

Dr. SCHULTZ. Absolutely. I've devoted the last 15 years of my life to that effort. So yes, I obviously think it's very, very important.

The CHAIRMAN. So if we even went to the point of trying to get some legislation on this to be sure that you're adequately funded, you would be in agreement?

Dr. SCHULTZ. Again, I think we would have to see and we would certainly welcome the opportunity to look at whatever ideas the Committee had and to be able to comment back.

The CHAIRMAN. Yeah.

Dr. SCHULTZ. Again, I would like to make sure that we do what is effective. Not just do something for the sake of doing something. I think one of the questions that was raised earlier in terms of how effective some of the drug oversight is. I think, frankly, that that question and the answers sort of resonated.

There's a lot of things that could be done. The question is, what should be done? How could we do it in a way that effectively achieves its result which is better public health.

The CHAIRMAN. As we commented on with the first panel, in most societies pharmaceuticals and medical devices are not advertised over television.

Dr. SCHULTZ. Right.

The CHAIRMAN. That's for a reason. You know, it's not a coincidence. That's for a reason.

Dr. SCHULTZ. Yeah.

The CHAIRMAN. Now if we're going to have that kind of advertising allowed in the United States, then isn't it logical that we need to regulate it to the extent that is necessary to protect the public?

Dr. SCHULTZ. I think we need to regulate it to the extent that's necessary to protect the public. I think that's absolutely a true statement. The question is, excuse me. The question is how do we do that? How do we do it efficiently?

The CHAIRMAN. Sure.

Dr. SCHULTZ. How do we actually address the concerns that are important and not spend a lot of time, frankly, having seen the amount of time that we spend looking at labeling and other promotional activities. You can spend an awful lot of time wordsmithing things in a way that sometimes I don't think can be as productive as—

The CHAIRMAN. Sure.

Dr. SCHULTZ [continuing]. Some of the other activities that we're engaged in. So I guess I'm agreeing with you that's it's an important problem. I would sort of put in a cautionary note in terms of making sure that whatever we do we think it through and make sure that it's really going to meet the needs of the American public.

The CHAIRMAN. I couldn't agree more. Just one last observation that you might want to make.

Dr. SCHULTZ. Sure.

The CHAIRMAN. Every last dime that's spent on advertising is past on to the consumer. The cost of medicine in this country, the cost of healthcare in this country is something that we're agitating and concerned about, as you know, at least as well, if not better than the rest of us. Efforts to try and contain the cost of medical care in this country is at the level of being urgent.

As we've said many, many countries don't allow any of this advertising on television. My guess is that in those countries people are living to the same age as they are here in this country. Do you have an observation?

Would you make an observation? Just a matter of what your long experience has taught you in this field? Is this advertising network we're spending so much money on and charging the customer directly for, in terms of the price that they pay for pharmaceuticals and medical devices?

Is this something that we should be talking about too? Just a matter of your opinion.

Dr. SCHULTZ. Sure. Yeah. Well, I mean I think it is obviously an important question. It's one that actually have been doing some thinking about since receiving your invitation. You know, again, I haven't seen all of the different ads for every different product.

But I guess I would sort of comment by way of example. There are a number of ads that I've seen recently for glucose monitors for people with diabetes. My sense is, again, opinion, not data driven. My sense is that reminding diabetics that monitoring their glucose and making sure that they see their doctor and control their diabetes is a good thing.

You know, whether how much those ads actually help to do that, you know, again, I don't have any data. But it seems to me that those kinds of reminders from whatever source they come from telling people that they need to take care of their chronic disease is probably not a bad thing. Some of the other ads, I think there is a range.

Obviously you saw a number of different ads ranging from wrinkle fillers to obesity treatments to cardiac stents. I think that within those products there's a range in terms of how useful they are in informing people about options and suggesting that they go see their doctor verses how un-useful they are in terms of perhaps over promoting and suggesting treatments that may not be that helpful. At the end of the day, as far as I'm concerned, you know, the decision in terms of what the best treatment for an individual patient is rests with the doctor and with the patient. I can say that as a former surgeon and as a regulator, I continue to believe that that's where the decision should be made.

The CHAIRMAN. Well, thank you very much. Your testimony has been extremely helpful. Appreciate your being here, Dr. Schultz.

Dr. SCHULTZ. Thank you.

The CHAIRMAN. We've come down to our last panelist. That is Stephen Ubl. Mr. Ubl is the President and CEO of the Advanced Medical Technology Association, normally called AdvaMed.

This is the world's largest medical technology association. AdvaMed's member companies produce medical devices, diagnostic products, as well as health information systems. Its members have produced nearly 90 percent of the healthcare technology purchased annually in the U.S. and more than 50 percent purchased annually all around the world.

So we're looking forward to your 5 minute testimony this morning.

STATEMENT OF STEPHEN UBL, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ADVAMED, WASHINGTON, DC

Mr. UBL. Thank you very much, Mr. Chairman. My name is Steve Ubl. I'm President and CEO of AdvaMed, as you said the Advanced Technology Association. We welcome the opportunity to testify this morning on DTC advertising for medical devices.

The medical technology industry is a critical component of the U.S. health sector. Constant innovation by our member companies leads to the introduction of new technologies that prevent illness,

allow earlier detection of diseases and treat patients as effectively as possible.

I've submitted my written statement. But I'd like to focus on four key points this morning.

First, AdvaMed's member companies believe strongly that direct-to-consumer advertising of devices must provide truthful and non-misleading information to consumers. As you are aware, device manufacturers are generally not heavily engaged in DTC advertising in comparison to the pharmaceutical industry. Most of our products are not sold directly to consumers.

In fact according to a Northwestern University report, medical device manufacturers spent only 116 million on advertising in 2005 compared to 4.1 billion for pharmaceutical ads. However, to further reaffirm our commitment we have guiding principles that will be presented to our board that strongly support responsible DTC advertising and compliance with the law. DTC ads should do the following in accordance with FDA policy: be truthful and not misleading, use consumer friendly language, disclose relevant risk information, encourage patients to speak with their doctors in more detail and follow all FDA and FTC statutes and regulations. I should also say we support FDA's full enforcement authority against companies that run ads in violation of the law.

In addition to complying with all relevant, applicable FDA and FTC policies, our principles go further. For example we share concerns about inappropriate use of celebrities in ads. That is why we believe such endorsements must reflect the honest opinion of the endorser, include statements that are substantiated as if they were made by the manufacturer and be representative of a typical patient experience or disclose when it is not.

Concerns have also been raised that companies should wait until physicians are trained on a new device before launching an ad. We support providing appropriate time to educate health professionals before an ad is launched taking into account the nature of the product, the risk benefit profile and needed training. We are also committed to ensuring that ads can communicate risk information in a way that consumers can best understand. We would welcome guidance from the FDA on how to tailor technical language on restricted devices to consumers. Such guidance should take into account the unique characteristics of medical technology.

The second point I want to emphasize is that DTC advertising in the device industry can benefit public health by informing patients of important potential therapies that they should discuss with their physicians. A 2005 Rand study found that patients receive the recommended standard of care only about half the time. The study found that 80 percent of those cases were due to under-treatment rather than over treatment.

In May a study published by the Journal of the American Heart Association found that only 51 percent of patients eligible for an implantable cardioverter defibrillator or ICD receive it. As Dr. Bozic mentioned in his testimony, a 2004 NIH report found that only 9 to 13 percent of patients who could benefit from joint replacement actually receive it. Whether the issue is artificial hips and knees, implantable cardiac technologies or diabetes control, far

too many patients do not receive treatment even when it is clinically indicated and potentially life saving or life enhancing.

Third, concerns about DTC advertising that have been raised in the drug context are in many cases, less relevant when applied to devices. Some have raised concerns that unknown side effects can appear when a drug is expanded beyond a clinical trial period. Unknown side effects can appear in devices too, but they are much less likely because devices, typically, do not act systemically and because the eligible population for a particular device is far smaller than for drugs.

In addition, whatever the validity of the concern that DTC advertising of drugs will cause doctors to ignore their professional best judgment and write a prescription the patient does not need or which is inferior to a competing treatment, it seems misplaced for devices. Unlike drugs, medical device treatments often entail complex procedures including surgery to replace body parts like hips and knees, connecting batteries to the heart or implanting the equivalent of metal scaffolding in a blood vessel. The idea that a patient would decide to undergo complex and invasive procedures based on an advertisement or that a physician would agree to perform them, even when it's inappropriate for the patient, is difficult to imagine.

My final point is that the FDA and FTC already have ample legal authority to regulate false or misleading advertising for medical devices. We believe that manufacturers are responsive and take action to address any issues raised by the FDA regarding an ad. For those who violate the law, the FDA has a broad range of remedies they can bring to bear from issuing a warning letter to removing a product from the marketplace.

We look forward to taking the feedback from this hearing to our board and working with you as you continue to explore this issue. I'd be happy to answer any questions the Committee might have.

[The prepared statement of Mr. Ubl follows:]

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SENATE SPECIAL COMMITTEE ON AGING

SEPTEMBER 17, 2008

STATEMENT BY

STEPHEN J. UBL

PRESIDENT & CEO

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

I'd like to thank the Committee for inviting AdvaMed to testify at this important hearing today on direct-to-consumer (DTC) advertising of medical devices and technologies. My name is Stephen J. Ubl, President and CEO of the Advanced Medical Technology Association, known as AdvaMed.

AdvaMed represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than $30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the $86 billion in life-saving and life-enhancing medical technology products purchased annually in the United States, and more than 50 percent of the $220 billion that are purchased globally every year.

The medical technology industry is a critical component of the U.S. health sector and is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading to new product iterations every 18 months. Constant innovation by our member companies lead to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

I'd like to focus my testimony on four key points.

First, AdvaMed's member companies believe strongly that direct to consumer advertising of devices must provide truthful and non-misleading information to consumers. As you are aware, device manufacturers are generally not heavily engaged in DTC advertising in comparison to the pharmaceutical industry, and most of our products are not sold directly to consumers. To further reaffirm our support for this commitment, we have guiding principles that will be presented to our Board that strongly support responsible DTC device advertising and compliance with the law.

The second point I want to emphasize is that DTC advertising in the device industry can benefit public health by informing patients of important potential therapies that they should discuss with their physicians. A 2005 RAND study found that patients receive recommended care only about half the time. The study also found that for patients who received deficient care, 80 percent of those cases were due to under-treatment rather than over-treatment.

In our nation's health care system, there are countless examples of patients who suffer from debilitating diseases even though therapies exist that could improve their lives and reduce their long term health care costs. The Arthritis Foundation recently found in a survey of arthritis sufferers that many mistakenly believe there is little that can be done to help their disease and improve their quality of life. Whether the issue is artificial hips and knees, implantable cardiovascular devices, or diabetes control, far too many patients do not receive treatment, even when it is clinically indicated and potentially life-saving or life-enhancing.

A third key point is that the FDA and the FTC already have ample legal authority to regulate false or misleading advertising for medical devices. As a practical matter, we believe that manufacturers are responsive and take action to address any issues raised by FDA regarding an

ad. As a legal matter, remedies range from issuance of a warning letter for compliance to injunctive relief to even seizure of product for removal from the marketplace.

Finally, concerns about DTC advertising that have been raised in the drug context are in many cases less relevant when applied to devices. Some have raised concerns that unknown side effects can appear when a drug is expanded beyond a clinical trial to the population at large. Unknown side effects can appear in devices too, but they are much less likely because devices typically do not act systemically, and because the eligible population for a particular device is far smaller than for drugs.

In addition, whatever the validity of the concern that DTC advertisement of drugs will cause doctors to ignore their professional best judgment and write a prescription the patient does not need or which is inferior to a competing treatment, it seems misplaced for devices. Unlike drugs, many treatments involving medical devices entail complex procedures, including surgery. Specifically, they can involve surgery to replace body parts like hips and knees, connecting batteries to the heart, or implanting the equivalent of metal scaffolding in a blood vessel. The idea that a patient would decide to undergo complex and invasive procedures based on an advertisement, or that a physician would agree to perform them even when it's inappropriate for the patient, is difficult to imagine.

Responsible Direct-to-Consumer (DTC) Advertising

Although the vast majority of our member companies do not engage in DTC advertising, AdvaMed strongly believes that ads should be designed to provide patients with clear and balanced information.

DTC ads should be truthful and not misleading. Examples of false and misleading representations include failure to revel material facts, lack of fair balance, and misleading comparative representations. Ads should use consumer-friendly language, disclose relevant risk information, and encourage patients to speak with their health care professional in more detail. Ads should follow all applicable Food and Drug Administration (FDA) statutes and regulations and applicable Federal Trade and Commission (FTC) statutes and regulations related to advertising.

A number of well-established FTC guidelines regarding testimonials and endorsements, including those by celebrities, should also be followed. For example, the endorsement must reflect the honest opinion, findings, or experiences of the endorser. The statements must be able to be substantiated as if they were made by the manufacturer. And endorsements must be representative of a typical patient experience, or the advertisement should contain a clear and conspicuous disclosure if it is not.

In addition, appropriate time should be spent educating health professionals about a device prior to launch of an advertising campaign. And we support FDA's full enforcement authority against companies that run ads in violation of FDA statutes and regulations.

The Role of DTC Advertising to Improve Public Health

Although DTC advertising of medical devices is relatively new, it can play a key role in improving patient access and quality of health care. When DTC ads are appropriately designed and in compliance with the FDA's requirements, they can raise patient awareness about debilitating and chronic diseases, educate patients about lifesaving and life-enhancing therapies that are too often underutilized, and encourage necessary dialogue between patients and their physicians about treatment options. It can also eliminate stigmas associated with older versions of technologies or procedures that once required invasive techniques.

DTC advertising can increase the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed or under-treated. A 2005 RAND study found that patients receive the recommended standard of care – including preventive care, acute care, and care for chronic conditions – only 54.9 percent of the time. The study also found that 80 percent of those cases were due to under-treatment rather than over-treatment.

In our nation's health care system, there are countless examples of patients who suffer from debilitating diseases even though therapies exist that could improve their lives and reduce their long term health care costs. The Arthritis Foundation recently found in a survey of arthritis sufferers that they mistakenly believe there is little that can be done to help their disease and improve their quality of life. Even with research showing the effectiveness of implantable cardioverter-defibrillators (ICDs) in preventing sudden cardiac death, many eligible patients still do not receive them.

An October 2007 study published in JAMA found that fewer than 40 percent of potentially eligible patients hospitalized for heart failure received ICDs, and women and African-American patients were significantly less likely than white men to receive an ICD. In all of these examples, if patients were armed with a greater recognition of both diseases and potential treatments, they could be empowered to seek care they need and to initiate fuller discussions with their physicians of their conditions and treatment options.

DTC advertising can also augment outreach efforts that companies undertake to educate physicians about new technologies. In fact, DTC is just a component of a broader campaign intended to raise awareness about the availability of a particular product. While physicians can stay informed about the latest medical advances through medical journals and outreach and training from manufacturers, physicians' time is stretched thin and it can be difficult to stay updated on the latest therapies. Patients who have seen DTC advertisements about a medical technology can often spur physicians to learn more about new technologies that could potentially benefit their patients.

While advertising to consumers often comes under fire for increasing utilization, these increases can lead to vastly improved health quality for patients. Artificial knees, for example, not only provide the gift of mobility and elimination or reduction in pain, but they save an estimated $66,000 in lifetime health care costs, primarily by avoiding or delaying institutionalization in a nursing home. Innovators are continuing to discover breakthrough technologies for conditions for which there is currently no treatment, as well as less invasive therapies with fewer complications. Shouldn't we want to encourage adoption of these technologies? DTC

advertising is one of the many ways to inform patients and physicians about these promising advances in health care.

The FDA and FTC Have Robust Authority to Oversee DTC Advertising of Medical Devices

While we believe that DTC ads can improve health care access and quality, AdvaMed members also take seriously our responsibilities to comply with all applicable legal requirements. That is why we fully support the Food and Drug Administration (FDA) and Federal Trade Commission (FTC)'s current regulatory authority over device advertising.

There is a long tradition in the regulation of medical device advertising and promotion. FDA regulates advertising of restricted devices and labeling of all devices. FTC regulates advertising of non-restricted devices. Each agency has regulatory enforcement authority providing them extensive control over the advertising process.

The Federal Trade Commission Act (FTCA) prohibits advertising that makes deceptive claims, fails to reveal material information, is unfair, or makes unsubstantiated claims. FTC also has developed guidelines in specific areas impacting advertising, including endorsements and testimonials. Regulatory programs and remedies of FTC can range from consent orders and cease-and-desist orders to affirmative ad disclosure and corrective advertising.

Under the Food Drug and Cosmetic Act (FDCA), any device is misbranded if its labeling is false or misleading. Furthermore, a restricted medical device (e.g. pacemakers, corrective contact lenses, hearings aids) is considered misbranded if its advertising, DTC or otherwise, does not include a brief statement of the device's intended uses and relevant warnings, precautions, side effects and contraindications. Device manufacturers vigorously adhere to the brief statement requirement to communicate relevant risk information related to the indication(s) being advertised.

We believe that complying with all these requirements ensures that consumers receive accurate and non-misleading information in DTC ads and that material facts are disclosed in a manner that is fairly balanced. Existing regulatory enforcement authority of FDA is broad and includes labeling review, meetings with ad sponsors, untitled letters, and warning letters. If warnings are unsuccessful, additional measures can include prosecutions, injunctions, and product seizures. Our member companies are committed to full compliance with FDA labeling and advertising requirements and the FTC regulatory program.

We also believe that FDA's regulatory authority over advertising appropriately recognizes the unique characteristics of medical devices that differentiate them from other treatments. Regulation must consider those distinctions rather than simply mirror that of prescription drugs. While pharmaceuticals involve a prescription for a course of pills that a patient takes individually, the selection and use of a medical device often requires the involvement of a number of health care professionals. Procedures often require surgical or other intervention by a physician who is trained in a broad range of treatment options and products and plays a key role in product selection.

In addition, evaluating whether a device therapy is appropriate for a patient can be a multi-step process involving health care professionals of different specialties. This should involve

substantial discussion with and education of the patient to adequately evaluate risk and benefit information. The limited use of DTC advertising by device manufacturers is indicative of the significant role physicians play in prescribing the use of their products. While DTC advertising can raise awareness of disease states and encourage patients to seek treatment, there are many steps before a patient receives therapy, ranging from consultations with multiple physicians, use of diagnostic tests, and discussion of the range of alternative treatments that might be appropriate.

Concerns about DTC Advertising of Medical Devices

We recognize that some policymakers and members of the public have raised questions about the use and impact of DTC advertising on safety and utilization. We would argue that these concerns have largely pertained to certain DTC ads involving pharmaceuticals, and that DTC advertising of devices is very different.

Many of the concerns about DTC advertising that have been raised in the drug context are less relevant when applied to devices. Some have raised concerns that unknown side effects can appear when a drug is expanded beyond a clinical trial to the population at large. Unknown side effects can appear in devices too, but they are much less likely because devices typically do not act systemically, and because the eligible population for a particular device is far smaller than for drugs.

Others have raised concerns about pharmaceutical DTC ads driving inappropriate demand, but device manufacturers generally do not sell devices directly to consumers - there are many intermediary steps before a patient can utilize a product. Unlike drugs, many treatments involving medical devices entail complex procedures, including surgery. Specifically, they can involve surgery to replace body parts like hips and knees, connecting batteries to the heart, or implanting the equivalent of metal scaffolding in a blood vessel. The idea that a patient would decide to undergo complex and invasive procedures based on an advertisement, or that a physician would agree to perform them, is difficult to imagine.

Others have argued that there should be a moratorium on DTC advertising for a specified period of time following product approval. However, a Federal requirement for a moratorium for DTC advertising of medical devices would ignore the unique nature of our industry. Most medical devices have a life cycle of 18 to 24 months and many of our industry's technologies are new devices that provide relief for patients who suffer from conditions that currently have no treatment. When a breakthrough technology is approved, DTC advertising can help raise awareness among patients and physicians about these new opportunities for treatment. A moratorium on DTC advertising could prevent patients from learning about therapies that could enhance or save their lives.

In comparison the life cycle of medical devices is significantly shorter than drugs. While a new drug may enjoy years of patent protection, as mentioned most medical devices have a life cycle of 18 to 24 months. If a restrictive moratorium is put in place, it would effectively block efforts by manufacturers to educate consumers about new products. That is why we support an appropriate time period to educate health care providers before the launch of a DTC advertising campaign – but ensures that the time period is flexible and determined by the nature of the product, including risk-benefit profile and needed training.

We also share concerns that have been raised about the risk of health-acquired infections. While this is not a device-specific issue, we agree it is a serious public health issue. According to the National Quality Partnership Surgical Care Improvement Project, an estimated 2.6% of nearly 30 million operations are complicated by surgical site infections each year. According to SCIP, a critical link in reducing the risk for hospital-acquired or nomoscomial infections are preventive care processes, including appropriate selection and timing of antibiotics, control of blood sugar and body temperature during surgery and other clinical processes. The GAO is conducting a study, per last year's FDA Amendments Act, to learn more about how and why nosocomial infections are acquired. This report should provide further insight into efforts to address this public health issue.

The device industry is committed to doing its part to address this problem. FDA-approved patient labeling contains more complete, detailed discussion of potential risks, including risks associated with all procedures. For products labeled as sterile, FDA requires that all the sterile processes and related manufacturing processes be validated. Furthermore, many implantable devices are delivered to the hospital in sterile packaging. Our industry also supports FDA's ability to issue a public health notification to better educate physicians, institutions, and the public about this important issue.

Conclusion

Again, we thank you, Mr. Chairman, for giving AdvaMed the opportunity to share our thoughts on direct-to-consumer advertising of medical devices. We believe that if designed appropriately and in accordance with current law, DTC advertising can help educate patients about disease, encourage them to seek treatment for conditions that might otherwise go untreated, and foster greater dialogue with physicians as their patients become more involved in their own health care.

We look forward to working with you and are happy to answer any questions.

The CHAIRMAN. Thank you, Mr. Ubl. You heard this morning about some of the shortcomings that are believed to be associated with DTC ads for restricted medical devices, both panels. As representative of the largest association of manufacturers of such devices, how do you respond to such concerns? What are you intending to do about them?

Mr. UBL. Well, I mentioned at the outset all the conditions that we believe should be a part of DTC ads. We've taken the additional step of developing principles we're presenting to our board. They go beyond FDA law and regulations in several respects—notably in the endorser issues that I raised, and the timeframe for education of practitioners before an ad is launched. We're open to taking the feedback of the Committee in terms of additional areas.

I would point out, however, that under-use was not mentioned in any of the earlier panels. It's a significant issue in terms of many medical technologies that patients could benefit from and DTC ads are an important source of that information.

The CHAIRMAN. Mr. Ubl, in your testimony you argue that manufacturers of the devices being discussed here today should adopt advertising practices to ensure that commercials featuring celebrity endorsers are representative of a typical patient experience. So I'd like to get your opinion of the following advertisement as we'll run it now. While you watch it, please keep in mind what we heard from the first panel with regard to the overly optimistic assumptions patients tend to form after seeing such advertisements. Let's look at the ad.

[Panel watching video.]

The CHAIRMAN. Mr. Ubl, is it typical for hip replacement patients to be able to play basketball, jump rope and surf as we saw depicted in this advertisement?

Mr. UBL. I'm not a physician. I think I would be best if I refrained from commenting on individual ads. I'd be happy to restate our views on these types of endorsements.

The CHAIRMAN. Go right ahead.

Mr. UBL. They should reflect the honest opinion of the endorser. They should include statements that are substantiated as if they were made by the manufacturer. They should be representative of a typical patient experience or disclosed when it is not.

The CHAIRMAN. Should medical devices be subject to the same kind of oversight as pharmaceuticals?

Mr. UBL. Sir, we believe, if you take a look at the FDA law regulations and guidance combined with the FTC equivalent that on the whole, the regulation on the pharmaceutical side compared to restricted devices is comparable, but for the exception that Dr. Schultz mentioned earlier in terms of submitting the ad concurrent with its launch. We will consider that issue.

But our view is that there are very few medical device and technology companies who are doing these ads. Those that are, are trying to do the right thing. We believe that the resources of the FDA are better trained where the need is most critical, which is on the enforcement side.

The CHAIRMAN. What comment would you be making to Dr. Schultz if he were sitting at the table and he said we need to have

the same kind of oversight and regulation for medical devices as we have for pharmaceuticals?

Mr. UBL. As I said, I think that I found much to agree with in Dr. Schultz's testimony. In reading it, I believe that, again, taken on the whole the types of requirements that apply to restricted devices and pharmaceuticals are quite similar, but for the exception that I mentioned. So I assume we could find much common ground in terms of the level of regulation.

I totally agree with his comment in terms of it's not whether, it's how, and the need to focus the Agency's limited resources on the most effective use for those resources and in our view that would be on the enforcement side. I should add that we're not aware of any company that when an FDA representative raises a concern with an ad that it's not addressed in a timely fashion.

The CHAIRMAN. Thank you very much, Mr. Ubl. We'd like to thank you as well as the rest of our witnesses for their presence here this morning. Clearly we have a subject and an issue that demands a lot more oversight and thought, ideas about where we need to go to be sure that people who are thinking about using medical devices get as much information as they need from the proper sources and that they're in a position to make the right decisions.

We're not yet of a mind to propose legislative solutions. It is not to say that we won't. But clearly this is something that we need to look at.

I've instructed my Committee staff to be very, very much on top of the issue. I would expect that we will be putting forth our opinions and issuing our suggestions so that we can stay on top of this issue. Thank you so much for being here.

[Whereupon, at 11:50 a.m., the hearing was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR ROBERT P. CASEY, JR.

I would like to thank Chairman Kohl for calling this important hearing to examine direct to consumer advertising (DTCA) for restricted medical devices. As this field continues to grow with advances in science and medical technology, we must ensure consumers receive the best and most accurate information available.

The United States is one of two industrialized nations, New Zealand being the second, allowing direct to consumer advertising for restricted medical devices. These are devices that require physician approval for uses such as artificial knees and hips, heart stents and implantable defibrillators. Other nations, such as Great Britain, restrict the provision of treatment information for patients to physicians only. Canada and the European Union require that advertising be reviewed by regulating agencies. Indeed, the United States may soon be the only nation to allow this practice as New Zealand is looking to strengthen its limitations on direct to consumer advertising and bring it more into line with Australian law.

In the United States, the Food and Drug Administration (FDA) has the responsibility of regulating direct to consumer advertising for restricted medical devices. Under the FDA guidelines advertising must not be false or misleading, it must be appropriately balanced between the risks and benefits of the device, it must include facts that pertain to how the product is used and it must mention every risk described in the product's approved labeling. The advertisements do not require approval by the FDA before being aired and the medical device section of the Federal Food, Drug and Cosmetic Act states that no regulations issued under that provision may require the Secretary to approve an advertisement's content before it is aired.

All patients should play an active role in their medical treatment plans and should be able to act as informed consumers asking questions about specific medical devices and technology. However, there is a concern that some direct to consumer advertisements give people false hope and lead them to believe that with this knee or that heart stent they will be able to lead a completely changed life and perhaps accomplish things that had never before seemed possible.

Modern medicine and the human body are both amazing things, but consumers must have the facts and a realistic prognosis of the potential that medical devices may offer them individually. I look forward to hearing the testimony of our witnesses and working with Chairman Kohl and other members of this committee on this issue.

In closing, Mr. Chairman, I want to again thank you for calling this hearing today. I look forward to continuing to work with you and with our colleagues next year.

MR. UBL'S RESPONSE TO SENATOR KOHL'S QUESTION

Question. Mr. Ubl, at the Committee's September 17 hearing I played for you a copy of an advertisement for Depuy's artificial hip product, which features celebrity endorser basketball coach Mike Krzyzewski of Duke. The advertisement depicted, among other things, people jumping into rivers, surfing, and playing basketball. You have represented to the Committee that AdvaMed is implementing a new policy with respect to direct-to-consumer advertisements for restricted medical devices, which include artificial hips. Is the Depuy advertisement that you viewed at the hearing in compliance with that new policy?

Answer. I cannot make a judgment about the accuracy of the ad nor whether the endorsements and testimonials depicted are representative of a typical patient. Such judgment would depend on knowledge of the product and patients' experience with the device, which is why we believe patients should talk to their physicians about their medical conditions and treatment options. I can tell you that I know people who have resumed their lifestyle, active or otherwise, after receiving artificial hips.

As mentioned at the hearing, we also believe that "endorsements and testimonials must be representative of a typical patient experience or the advertisement should contain a clear and conspicuous disclosure." AdvaMed is in the process of reviewing guiding principles on DTC device advertising and we will keep the Committee apprised of developments.

Statement of the Sudden Cardiac Arrest Association Before the Senate Special Committee on Aging

Subject: Direct Marketing to Consumers of Medical Devices

September 17, 2008

Chairman Kohl, Ranking Member Smith and members of the Committee:

The Sudden Cardiac Arrest Association (SCAA) appreciates the opportunity to share its thoughts with the Committee on the subject of direct marketing to consumers of medical devices.

For the Committee's background, SCAA is the largest national organization singularly devoted to preventing sudden cardiac arrest (SCA). Our network of local chapters and affiliates stretch from Maine to Hawaii, and our members reside in 46 states and include sudden cardiac arrest survivors, patients at risk, emergency medical professionals, physicians, nurses and others touched by SCA. Many of our members are alive today because of medical technology and medical devices:

- their lives were saved by the shock of an automated external defibrillator (AED)
- their heart's rhythm is protected by an internal cardioverter defibrillator (ICD)
- their on-going health care is managed in part by a remote monitoring system of their ICD that allows virtually instantaneous communication and evaluation by their physician.

Sudden cardiac arrest is the nation's leading cause of death, killing more than 300,000 people each year. That is more than the number of deaths caused by lung cancer, breast cancer and HIV/AIDs *combined*. SCA is different than a heart attack, and the public was most recently educated on the condition after their news coverage of Tim Russert's untimely death. But sadly, the public's understanding of SCA remains dismally low.

SCA victims require the almost immediate shock of a defibrillator – either externally by an AED or internally by an ICD – to restore the heart's natural rhythm. Otherwise, SCA victims quickly die, usually before they reach the hospital. The national survival rate for SCA is only in the 5-7 percent range.

The responsible marketing of devices such as AEDs, ICDs and remote monitoring systems are important public education tools for SCA awareness, response and prevention. Many victims of sudden cardiac arrest would not die if they were properly treated – either through quick emergency response or preventative therapy. SCAA's position is that AEDs should be widely available where people gather, and even in

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people's homes. While members of this Committee and your collective staff are provided quick access to AEDs though the wide deployment of these devices throughout the Capitol complex, there are thousands schools, offices, churches, health/sports facilities and other venues where they should be placed. Our organization advocates their wide deployment and we are supportive of all device manufacturers marketing their products and their devices' public benefits in mainstream media and other advertising venues.

Furthermore, ICDs cannot be purchased or used without the involvement of a physician (through the surgical implantation of the ICD). While we certainly do not support the second-hand sale of any such prescription medical devices on Ebay, Craig's List or other such marketplaces. SCAA does support corporate best practices that involve the internal review of the advertisements to make sure they are consistent with FDA-approved use and labeling requirements, are risk-balanced, and distinguish between primary and secondary prevention. We would strongly encourage the Committee to carefully balance the public benefits against anecdotal and/or isolated incidents.

Ultimately, the patient/consumer and his/her family are in control of their choices, treatment options and purchases. No one is coerced into buying an AED – even though we believe that many business, schools and other institutions ***should*** purchase them. And implantable cardiac devices are a treatment from the result of multiple physician-patient consultations. In all cases, the Internet provides ample, instantaneous and free information for all consumers to fact check, compare, refute and evaluate before making a decision.

Respectfully submitted,

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