TRIBUTE TO REVEREND WILLIE JAMES

● Mr. LAUTENBERG. Mr. President, I rise today to recognize the great work of a civil rights pioneer and chapter president of the National Association for the Advancement of Colored People of Willingboro, New Jersey, Reverend Willie James, on the occasion of his receiving the award for exemplary community service.

Reverend James began his work for civil rights in 1958 when he attempted to buy a house in Willingboro's Levitt community. He was told that houses would not be sold to African-Americans. Reverend James decided to sue. Two years later, the United States Supreme Court officially integrated Willingboro, enabling Reverend James to become one of the community's first African-American residents.

In 1974, work demands forced Reverend James to move to Rhode Island. While in Rhode Island, Reverend James joined a statewide commission that studied disparities in white and minority prison rates than whites.

Eventually Reverend James returned to New Jersey where his level of activism flourished. He became president of the Willingboro chapter of the NAACP. During his time as president, Reverend James made great progress researching the issue of disproportionate African-American male imprisonment.

In the recent election, Reverend James and the local chapter of the NAACP worked on motivating minorities to vote. Reverend James is a recipient of more than 30 local and national awards for his commitment to public service.

I am pleased to honor Reverend Willie James on this joyous occasion. His family, his friends, and his community are indebted to him for his unyielding service. This honor is richly-deserved. I salute him on yet another great achievement.●

IN RECOGNITION OF MR. WOODROW W. WOODY

● Mr. LEVIN. Mr. President, on Thursday, November 16, 2000, the people of Michigan, will pay tribute to Mr. Woodrow W. Woody, president and owner of the longest running car dealership in the Nation—Woody Pontiac Sales, Inc. Mr. Woody, who continued active participation in the business, until he was 92 years old in June 2000, when he officially closed the Pontiac dealership he opened in the city of Hamtramck, MI in 1940.

Mr. Woody has come to be known as the pillar of his industry. In 1966, his dealership hit its peak year with the sale of 2,200 cars. Revered by his peers and the people of Michigan, he was inducted into the Automotive Hall of Fame. Over the 60-year operation of his dealership, Woody, as he is called by friends and family, estimates that he sold over 100,000 Pontiacs, one of General Motors' leading products. He says his success is due to his genuine love of life and people.

This immigrant from Lebanon, embodies the ultimate success story of the American dream. Much of why he is being honored is because of his dedication and loyalty to the citizens of the city of Hamtramck and his beloved Lebanon. When the economy recessed and auto sales reflected a downturn, Woody never considered moving his dealership from the community that supported him through prosperous times. Hailed for his philanthropic activities, he spearheaded a drive to build a new facility for the Hamtramck Public Library. In addition, he has worked with Junior Achievement and the Rotary Club for more than 50 years accomplishing projects which support community growth. Woody has also been just as committed to the people of his homeland, where he has built a school and medical clinic.

Although Woody promises to continue his work in the community, interacting with various civic and fraternal organizations for the good of the community, the industry has lost its senior statesman and he will be sorely missed. We all wish Woody continued health, happiness and prosperity in the years ahead. I am sure my colleagues join me in the celebration of the life of Mr. Woodrow W. Woody, extending to him the good will and wishes of the Senate.●

RECOGNITION OF BRIAN KAATZ, PHARM. D.

● Mr. JOHNSON. Mr. President, I rise today to express my appreciation for the contributions of Brian Kaatz, Pharm. D. who has worked as part of my staff for the past three months as a senior Fellow. Brian's expertise in the area of pharmacology has made him a tremendous asset to my legislative staff, and I am fortunate to have had his assistance. When he returns to the Department of Clinical Pharmacy at South Dakota State University in December, I know he will be missed immensely by me and my entire staff.

Fellows are often considered secret weapons to the Members they assist. Brian has been no exception. He came to my office with a distinguished professional career accompanied by a wealth of experience within the pharmacy industry. While his expertise lies in clinical pharmacy, Brian's interests range from issues involving infectious diseases and use of antibiotics, nutrition, health care ethics, drug policy and roles for pharmacists.

Currently a Professor and Department Head of Clinical Pharmacy at the South Dakota State University, Brian has had a career filled with accomplishments. He has been president of the South Dakota Society of Hospital Pharmacists, a member of the committee that re-wrote the pharmacy practice act passed by the South Dakota legislature in 1992, an official delegate several times to the American Society of Health-System Pharmacy annual meeting, and served as a consultant to several South Dakota hospitals and law firms. Additionally, Brian has authored or co-authored approximately twenty-five professional articles and is currently the editor of the South Dakota Journal of Medicine's Pharmacology Focus column, published monthly in South Dakota's Physician Journal. He has made numerous major presentations both regionally and nationally, and received several awards over the years for his notable career.

Throughout the past three months, Brian has worked on a number of projects in my office dealing with pharmacy and health care. Brian led research efforts regarding a comprehensive study comparing prescription drug prices throughout South Dakota and the impact of rising drug costs on those without insurance. Many millions of Americans, both Medicare age and younger have either inadequate or no prescription drug insurance at all. There are roughly 39 million Medicare beneficiaries in this country, one third of whom have no prescription drug coverage. At a time, when drug prices are rising at rates far greater than the rate of inflation and seniors around this country are forced to choose between buying food or pills, we have an inadequate Medicare program that provides no coverage for prescription drug costs. The study that Brian spearheaded provided me with crucial data and real life stories depicting the impact of this issue for South Dakotans, young and old alike. Brian's research furnished my office with up-to-date and unbiased information that enabled me to communicate effectively with my constituents, especially pharmacists, during this time. Unfortunately, Congress was not able to come to an agreement on how we provide Medicare beneficiaries with prescription drug coverage, therefore the information that Brian compiled for me will be critically important as I work on this issue in the 107th Congress next year.

Brian also facilitated discussions with the Government Accounting Office, GAO, on two subject matters involving direct-to-consumer advertising of prescription drugs and conflict of interest matters involving the Food and Drug Administration's Advisory Committee members. The research Brian conducted in these two areas will provide me with the basis for further discussions with GAO and congressional committees seeking hearings into these matters. Brian previously authored and co-authored two articles specifically on the subject of direct-to-consumer advertising and has completed extensive research in this field.

I ask to have the contents of these two articles printed in the RECORD following completion of my statement.

One of the most important tasks as a Senator is to communicate with your constituents back home. Balancing my

duties in Washington with my schedule in South Dakota is often challenging due to uncertainties of the Senate schedule. Brian's established relationship with the South Dakota Pharmacist's Association, South Dakota Board of Pharmacy and several national pharmacy organizations was extremely crucial to his work with my office. He was able to advance discussions surrounding several issues with these groups which will aid me tremendously in my future work with prescription drugs, roles of pharmacists and other health policy matters.

Brian can take pride in his career and dedication to health care issues. He is a recognized health care expert, an educator, an author, an advocate and a friend. I wish to express my deep gratitude to Brian for a job well done. I wish him the very best in his future endeavors.

The articles follow.

[From the South Dakota Journal of Medicine, Dec. 1998]

DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: AN ETHICAL PERSPECTIVE

(By Brian Kaatz)

There is no doubt to anyone who reads this that the detailing and promotion of prescription drugs is big business. Thousands of sales representatives are employed and millions of dollars are spent annually to explain the putative advantages of certain products over others.

Notably, the effort by pharmaceutical manufacturers to expand market share of certain targeted prescription drugs has traditionally been directed solely to health professionals. This has changed in a big way.

Newspapers, magazines, and television are inundated with prescription drug promotions aimed at attracting the attention and interest of the public. Advertisements are intended to stimulate the individual interest of patients, which then potentially will result in inquiries (or demands) directly to physicians for that product. This approach may seem entirely satisfactory to the general public, but it is potentially problematic from several standpoints.

Even under the best of circumstances, most clinicians will admit that their knowledge of new drug products is far from complete. Ideally, a perspective of when or if to use a new product will come from careful surveillance of the primary literature, consultation with a respected and knowledgeable colleague, or from an unbiased, current review of a specific category of drugs. Many physicians pragmatically approach a new drug intending to be ''neither the first nor last'' to use it. This approach could understandably be thwarted if a number of patients persistently request a particular product as a result of the tried-and-true marketing approach of repetitive media encounters and high product visibility.

A patient may not be understanding if her physician tells her that he has no experience with a drug when at the same time the patient has seen it advertised maybe 20 times in the last two weeks. What is wrong with my doctor? Doesn't he watch TV?

The result may be subtle pressure or even coercion to prescribe the drug in question.

Tens of millions of dollars are spent advertising drugs like Claritin, Rezulin, Zocor, and Pravachol. Apparently, this approach has been especially successful since August of 1997, when the FDA allowed televised advertisements to be exempt from detailed descriptions of drug risks. This ruling at least relieved the viewing public from the sometimes bizarre, oblique ads that were seen prior to this, when requirements limited drugs to a name but no detail as to its use. Even relatively astute observers were sometimes confused about the intent of these commercials.

Now, patients and other interested parties are referred to the Internet or other sources ''for more information,'' though they obviously are already headed down the road of special interest in that drug.

Beyond the easy questions that would ask, why can't these tens of millions of dollars be used to lower drug costs, or be put into research for new and safer pharmacologic entities, what of the ethics of direct-to-consumer advertising?

Patient autonomy has been argued elsewhere as being the preeminent ethics principle. There is a strong case for patients knowing as much as they can reasonably understand about disease processes and medication risks and advantages. There is also a strong case for patients being actively involved in their own therapeutic journeys and fully participating in these kinds of decisions. But can we relate direct-to-consumer advertising with true patient autonomy? Is advertising valuable in the effort to develop autonomous decision making? There is a case for answering these questions in the negative.

It must be remembered that patient autonomy does not begin and end with the simple act of a patient making a decision. To the contrary, autonomous decision-making occurs only when there is a fully informed decision-maker. Autonomy is based upon that important element. Thus, one can readily see that a brief, colorful advertisement by itself offers little in the way of full disclosure and does not contain the complete tools necessary to make an autonomous decision.

It perhaps is particularly important in these situations for doctors to maintain a healthy beneficent attitude which could result in a patient receiving a drug with which his physician is familiar and comfortable, rather than the one that is most persistently on prime time. It is not a disservice to attempt to dissuade a patient who is only partially armed with knowledge from committing to long term therapy with a potentially suboptimal drug. And it is not true autonomy that is being exerted when a patient presses for that drug. What might at first glance seem like autonomy lost is actually beneficence gained.

[From the Journal of Medical Humanities and Bioethics, Spring/Summer 1987]

THE PHYSICIAN AND THE PHARMACEUTICAL DETAIL MAN: AN ETHICAL ANALYSIS

(By Jerome W. Freeman and Brian Kaatz)

The principal focus of medical practice should be the patient's interest. The physician's conduct in the clinical realm should consistently reflect this. Arguably, this ideal is not always realized. An example of a circumstance in which the patient's interest does not predominate occurs in the context of the physician's interaction with pharmaceutical companies. These companies have a variety of marketing techniques directed at physicians in order to promote prescription drugs. This essay will explore the ethical implications of one aspect of these marketing programs—namely, the role of pharmaceutical salespersons. These men and women have a variety of titles including ''sales representative,'' ''medical sales liaison,'' and ''detail man.'' The latter term is commonly used, apparently as a reflection of these representatives' efforts to provide physicians with details or data about drugs.

Before attempting to assess the ethical implications of pharmaceutical companies' marketing techniques, a specific inquiry into the goals and ideals of medical practice is warranted. Most physicians take for granted the notion that the patient's interest is of primary importance and that moral dilemmas in medicine are appropriately resolved through a patient-centered ethic. Kass reflects this view when he notes that ''loyalty to the patient must be paramount, first, because the mysterious activity of healing depends on trust and confidence, which is lodged by the vulnerable and dependent patient with the physician, in the very act of submitting to his care.''

The basis for such a patient-centered ethic derives from, and is consistent with, basic ethical principles. Veatch' characterizes these principles as the ''basic social contract,'' and he points out that diverse ethical systems frequently arrive at a similar core of basic principles and derivative rules. Often such principles include autonomy, nonmaleficence and beneficence. On the basis of such articulated principles, society can proceed to define the nature of relationships between a profession and society. Veatch argues that this process can establish that a contract or covenant exists between the physician and society and between the physician and the individual patient. This covenant arguably mandates a patient-centered ethic in medicine, guided by adherence to those basic ethical principles society has defined and endorsed.

Of these major principles, autonomy dictates that the physician treat the patient with dignity and respect and that the patient be allowed to participate in his or her own health care decisions. Nonmaleficence warrants that the physician endeavor to avoid causing the patient harm through his actions. The sense of this principle, thought to derive from the Oath of Hippocrates, is often quoted in the Latin phrase primum non nocere (first, do no harm). Beneficence stipulates that the physician work actively to benefit the patient by contributing to his or her health and welfare.

In this ethical framework, it is possible to characterize the impact that pharmaceutical marketing techniques have on the physician-patient relationship. The pharmaceutical detail man promotes his company's products to physicians in a number of ways. He or she frequently calls on physicians in their offices and also meets with them in the hospital. Often in hospitals the representatives from various pharmaceutical companies participate in a rotational schedule for operating a drug display in a prominent location, usually near the physicians' entrance. A detail man frequently has one or two drugs to promote actively, and literature and visual displays which describe these agents. Each salesperson argues why his or her drugs are better than competitors' formulations. In addition to a verbal message and printed information, the detail man often has various ''gifts'' for the physician. Pens or writing pads inscribed with a particular drug name are common. Gifts also include free texts, medical equipment (such as reflex hammers and penlights), and medical bags (typically given to graduating medical students). Drug samples are frequently offered. In addition, the detail man may coordinate more elaborate gratuities such as cocktail parties, refreshments at medical meetings (such as those of state medical association groups) and the sponsorship of medical symposia. Specific examples of such marketing efforts are illustrative.

One of our community hospitals was approached by a drug salesperson to participate in a study involving an antibiotic that was on the market. This drug's utilization had been minimal because of increased cost to the patient and the fact that it offered no

substantive therapeutic advantage. The proposal extended to the physicians and hospital was to use the drug on a given number of patients, at the patients' expense. Physician participants in the study were to be ''reimbursed'' 125 dollars for each patient enrolled. This sum was designated to cover ''expenses'' associated with the study.

A second example of an elaborate gratuity system has recently been utilized in our community. Selected physicians were invited by a pharmaceutical company's detail man to an expense-paid seminar in a popular vacation city. The meeting focused on a new antihypertensive drug (at the time, this drug company had the only formulation of this drug on the market). The educational component of the meeting was judged to be very good by the physician participants. This promotional package included airfare for the physician, lodging for the physician and spouse, meals, a cocktail party, and an evening of dining and dancing on a chartered river boat. In the year following this event, two other pharmaceutical companies have offered similar meeting packages to physicians in the community.

Such promotional efforts are clearly expensive. For instance, it has been estimated that each visit by a detail man to a physician costs the pharmaceutical company 75 dollars. Despite the expense, however, drug companies have found that the use of the detail man is the most effective means of promoting their products. These companies often prefer to characterize their detail man as ''service representatives'' purveying information, rather than as salespersons. One company not only requires the detail man to attend four tutorials a year, but also gives pharmacology tests to all its representatives quarterly. But such training does not negate the fact that, in practice, detail men function as aggressive, effective salespeople. Indeed, most of them are at least partially reimbursed on a commission basis. Their success as pharmaceutical representatives is clearly dependent upon their ability to sell drugs. Those drugs which representatives emphasize at any given time reflect corporate decisions based on such factors as competition, quotas and the patent status of the drugs.

Given the stated nature of the physician-patient covenant, the type of relationship that frequently exists between the physician and the detail man is ethically troublesome. More specifically, that relationship appears to violate all three of the basic ethical principles previously discussed. By virtue of the principles of autonomy and beneficence, the patient has a right to expect that he or she will be treated with dignity and respect. He or she expects to receive the best possible treatment the physician can generate. The patient has a right to assume that the physician's therapeutic decisions are based solely on scientific medical knowledge, unbiased by extraneous factors or inducements. Thus, the very nature of the physician-patient covenant, and the principles that underlie it, would seem specifically to preclude the physician from basing a drug-prescribing decision on factors other than what is objectively best for the individual patient. To the extent that the physician decides to try out a new drug or opt to prescribe regularly a medication simply because he likes a detail man or because he is consciously or unconsciously affected by his or her various inducements and salesmanship, the physician would seem to be violating the patient's trust. One wonders what a patient's reaction would be if he or she were explicitly aware that such interactions and inducements existed.

In addition, the principle of nonmaleficence can be violated by the physician-detail man relationship. Often the new drug formulations which are promoted offer no meaningful advantage over older drugs. Yet, in taking them, the patient risks the possibility of experiencing adverse effects as yet undiscovered or not well publicized (even when the drug has been approved by the Food and Drug Administration). The recent controversy surrounding the drug Oraflex constitutes such an example. This drug was vigorously promoted as a new, very effective agent for arthritic symptoms. Shortly after its release, this agent was removed from the market because it was associated with serious liver toxicity in some patients. Moreover, the patient usually pays considerable financial premium when a new drug formulation is used. Invariably, the newer drugs being marketed are significantly more expensive than older, and sometimes equally effective, drugs whose patents have expired (rendering them much less profitable to the pharmaceutical company). Again, the average patient has no insight into this fact. He or she certainly is not usually afforded the opportunity to decide autonomously whether the drawbacks and risks of a new drug formulation render it less advantageous than other, longer-established drugs. And indeed, even if the typical patient is given some knowledge of drug options, he or she lacks the expertise to participate seriously in the decision of which drug to employ. In fact, it is the physician alone who ordinarily must make the determination of which drug to employ. If this decision is based on sound, scientific data, the choice of a new and more costly drug may clearly be justified. However, to the extent that the physician does not rely on objective medical data (as published in medical journals or discussed at medical meetings), but rather derives his information from the drug companies' own representatives, a potential conflict of interest exists.

Pharmaceutical companies might respond to this assertion by observing that in our free enterprise system there is nothing wrong with vigorously marketing one's products. Indeed, in the open marketplace it is, of course, common to offer a variety of inducements, including rebates, coupons, gifts and other types of price reductions. However, this situation is not analogous to the relationship between the detail man and the physician. In the ordinary marketing arena, companies attempt to influence the purchaser and user of various products. This is categorically not the case in the relationship between the physician and the pharmaceutical companies. The patient is the passive, dependent recipient of the physician's practice decisions. By virtue of this fact, as well as the implicit covenant which exists between the physician and the patient, the physician has an obligation to strenuously avoid basing any prescription decisions on factors other than the strict medical indications for those drugs. To the extent that the physician is either unconsciously or manifestly induced to use the drugs of a given detail man or pharmaceutical company, in the absence of strict medical indication, a significant ethical problem exists.

The implications of this analysis are clearly troublesome. It would appear that the current standard of medical practice, in terms of the relationship between the physician and the pharmaceutical detail man, may readily promote outcomes not in the patient's best interest. Since the physician-patient covenant and the ethical principles which underlie it warrant that the patient's interests should be the prime focus of medicine, significant changes are warranted in the methods which pharmaceutical companies employ to market their drugs. Currently, pharmaceutical companies, medical organizations and individual physicians are clearly party to, as well as beneficiaries of the present marketing techniques. Thus, there are powerful incentives to maintain this longstanding system. The pharmaceutical companies' profit makes it understandably difficult for them to endorse sweeping changes in their current, successful marketing practices. Many medical organizations and their scientific journals are largely dependent on the advertising which is purchased by the drug companies. And certainly the individual practitioner, too, clearly benefits from the current system of gifts and gratuities.

Changes in the present system of drug marketing will doubtless come slowly. Most likely, improvements will evolve only as individual physicians become better educated about these ethical concerns and committed enough to demand alterations in the present marketing practices. The individual physician's role in this process should not be viewed as an optional one. Rather, the physician is ethically mandated to work for change in this realm of drug marketing. This responsibility derives from the physician's clinical covenant with the patient and the moral principles which underlie it.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Ms. Evans, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

MESSAGES FROM THE HOUSE

Under authority of the order of the Senate of January 6, 1999, the Secretary of the Senate on November 3, 2000, during the recess of the Senate, received a message from the House of Representatives announcing that the House has passed the following joint resolution, in which it requests the concurrence of the Senate:

H.J. Res. 124. Joint resolution making further continuing appropriations for the fiscal year 2001, and for other purposes.

ENROLLED BILL SIGNED

Under authority of the order of the Senate of January 6, 1999, the Secretary of the Senate on November 3, 2000, during the recess of the Senate, received a message from the House of Representatives announcing that the Speaker has signed the following enrolled bill and joint resolution:

S. 2413. An act to amend the Omnibus Crime Control and Safe Streets Act of 1968 to clarify the procedure and conditions for the award of matching grants for the purchase of armor vests.

H.J. Res. 123. Joint resolution making further continuing appropriations for the fiscal year 2001, and for other purposes.

Under authority of the order of the Senate of January 6, 1999, the enrolled bill was signed by the President pro tempore (Mr. THURMOND).