

In an effort to improve the health and safety of patients using a pharmaceutical product that has been linked to several major side effects, I recently joined with my friend and colleague Congressman BART STUPAK of Michigan to introduce this legislation that will establish a comprehensive patient registry for users of the drug Accutane and its generic forms.

Accutane was approved for use in treating severe acne in the early 1980s. Today, more than 1 million prescriptions are approved each year, and not always for the serious cases of acne for which the drug is intended. The Food & Drug Administration states that, "Accutane may cause depression, psychosis, and rarely, suicidal ideation, suicide attempts, and suicide." Additionally, the makers of the drug state that "there is an extremely high risk that a deformed infant can result if pregnancy occurs while taking Accutane in any amount, even for short periods of time."

Four years ago, Congressman STUPAK had to endure the tragic suicide of his teenage son, who was using Accutane at the time of his death.

Despite the fact that the significant and serious side effects linked to Accutane are well known, the Food and Drug Administration has yet to mandate a program to better monitor the use of this drug and to document its effects in patients. Such a registry has been recommended by FDA advisory panels on two separate occasions.

Mr. Speaker, our bill is common sense legislation that will build upon a safety plan first proposed by the makers of this drug themselves. It will still permit doctors to prescribe Accutane, but will also institute several additional patient safety and protection measures and ensure patients and their families know the full risks before beginning treatment.

H.R. 4598 will permit physicians to prescribe Accutane only for "severe, recalcitrant nodular acne" that has been unresponsive to other forms of treatment. Severe acne is the condition for which Accutane was originally approved by the FDA to treat.

For patients with severe acne, Accutane may be the only medication that can successfully treat their affliction. But in far too many cases, Accutane is prescribed in an overly cavalier manner, and patients are being placed at risk to the drug's potential side effects for no medically valid reason. Many teenagers suffer from acne, and doctors and patients need to be cautious and not treat this drug lightly.

The legislation will also register all physicians and pharmacists who prescribe and dispense the drug, and institute an education campaign to ensure these providers are well-informed about the potential risks associated with Accutane. All patients will also be educated and be required to receive similar information before starting treatment with Accutane and throughout the treatment regimen.

Prescriptions will only be written for 30 days and will not be permitted via the telephone, Internet, or mail. Female patients will also have to undergo a monthly pregnancy test before receiving a renewal on their prescription, and all patients will be required to take a monthly blood test.

The makers of the drug and all practitioners who dispense Accutane will also be required to file prompt reports with the Department of Health and Human Services anytime they learn of a negative reaction, including a death, that occurs in a patient while using Accutane.

REMARKS BY CHAIRMAN DORCAS HARDY, VA TASK FORCE ON VOCATIONAL REHABILITATION AND EMPLOYMENT

HON. HENRY E. BROWN, JR.

OF SOUTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 22, 2004

Mr. BROWN of South Carolina. Mr. Speaker, Honorable Dorcas R. Hardy recently chaired the Vocational Rehabilitation and Employment Task Force of the Department of Veterans Affairs. The Task Force issued its report in March 2004, and furnishes an excellent road map on how VA can place a stronger emphasis on long-term sustained employment for disabled veterans who are vocational rehabilitation participants. I was especially impressed with the section entitled, *More Challenges Await: A Final Word from the Task Force Chairman*, and commend it to my colleagues as an example of Ms. Hardy's wisdom and foresight:

MORE CHALLENGES AWAIT: A FINAL WORD FROM THE TASK FORCE CHAIRMAN

Addressing the benefit, rehabilitation, and employment needs of persons with disabilities—and especially veterans with service-connected disabilities continues to be difficult, and often controversial. One thing is certain: The Department of Veterans Affairs cannot afford to fail the veteran who has given so much in the service of our Nation in previous wars and now in this age of terrorism.

There is no doubt in my mind that VA's Vocational Rehabilitation and Employment Program can become the best public rehabilitation program in the country, given appropriate resources and leadership. The new comprehensive, integrated 21st Century VR&E Employment-Driven Delivery System, which is proposed by the Task Force, builds on the strengths of the past and provides a continuum of service delivery, from military service to career counseling, appropriate retraining, and education, to employment or transitional independent living services with the ever-present goal of employment. The new system can provide the answer to a disabled veteran's transition to civilian society—a job.

Employment program will necessitate a major shift in attitude and approach. The current reality is that the VR&E program—despite the legislation of 1980—continues to operate as a VA education benefit for disabled veterans. It provides a larger stipend than the GI Bill program, and is accompanied by some counseling, as necessary. The new program, on the other hand, addresses the continuum of "life cycle" needs that a veteran with disabilities experiences, of which education may—or may not—be a necessary part. The focus will be the rehabilitation and employment needs of the 21st century service-connected disabled veteran.

Because the United States is at war, and will likely be in conflict situations for the foreseeable future, there must be a sense of urgency on the part of the entire Department as well as the Vocational Rehabilitation and Employment Service to create this new 21st century service delivery system.

I respectfully suggest that no more reports or discussions are needed, just immediate and concrete actions that are supported by the Administration, the Department, and the Congress. If this vital program, with its potential for becoming the most outstanding vocational rehabilitation system within the federal government, is unable to quickly and

effectively serve the 21st Century veteran, then one must consider other options. These options include: (1) contracting the program out with clear and stringent requirements to follow the employment intent of the law, or (2) recognizing that the mandated employment focus of the program is not possible and reintegrating VR&E into the Education Service of the Veterans Benefits Administration, adding an additional stipend for disabled veterans.

Having served in various state and federal governmental positions, including Commissioner of Social Security and Assistant Secretary of Human Development Services, I have worked with numerous social services policies and programs. Cash benefit services, such as the VA Compensation and Pension Service or Social Security provide support through direct payments. These programs require development of automated claims processing methodologies. Direct and personal services are those provided by VR&E or social service agencies. Different skills, personalities, and approaches are needed for each part of the delivery system. VR&E stands as an island in the sea of the Veterans Benefits Administration, a claims processing organization. VR&E is not connected to the claims processing functions, nor do other business lines have any particular appreciation or understanding of its function. Both cash and direct benefits are needed to support the veteran. Development of a seamless, integrated delivery system is the challenge.

Many have suggested that the entire VR&E program should become a part of the Veterans Health Administration, which has more of a hands-on service delivery focus. Just as the Task Force rejected the idea of moving the VR&E Independent Living program to VHA at this time, that same thinking can be applied to moving all of VR&E to VHA. VR&E needs to address its own shortcomings first, wherever it is housed, before participating in another reorganization.

If implemented with commitment and enthusiasm, the Task Force's recommendation to rebuild the VR&E Service can be successful. Building the new service delivery system cannot be done slowly, nor sequentially. It must be driven with clear and focused timeframes; and it must be done believing that each veteran's future depends upon an effective new approach. Leadership and management will be key; timeframes that some may deem unreasonable should become standard; processes must be streamlined and supported by technology; and veterans must recognize that they, too, have an individual responsibility to complete their vocational rehabilitation plan and secure employment in a timely manner.

FUTURE POLICY CONSIDERATIONS

Throughout the discussions and deliberations of the Task Force, several broad policy issues were raised that were not thoroughly addressed, either because they were not directly within the scope of this Task Force's work or, in several cases, they were far more complex than our time permitted. Some issues were just too controversial at this particular point in time, but their "tipping point" will come and thoughtful policymakers and managers should be prepared to consider their breadth, shape, and impact upon VR&E. As the Veterans Benefits Administration proceeds to modernize VR&E, these longer term policy considerations, which cross the business lines of VBA, should be discussed and addressed. Each issue below will arise in the foreseeable future; each issue will have a significant consequence for the successful future of a 21st century VR&E program.

ROLE OF COUNSELING AND TRANSITION ASSISTANCE IN THE VETERANS BENEFITS ADMINISTRATION

Historically, VBA had a focus on personal counseling about requested benefits and services through face-to-face contact with the veteran. Today, the Compensation and Pension Service provides outreach services to veterans through the Veterans Service Centers but the focus is "you are entitled to benefits from the VA and here is the claim to file." This is not counseling in the traditional sense, rather a method to ensure that veterans receive cash benefits to which they are entitled. Since the VR&E Program is the only benefit that is provided face-to-face to the veteran, VR&E, with its professional counseling staff, should provide all outreach services to veterans, regardless of whether or not the veteran is disabled. A veteran with financial or life cycle or any other issues should be able to access counseling services at a VR&E office. Such a policy may necessitate additional resources beyond what is recommended at this time to rebuild the VR&E program.

NEED FOR NEW PROGRAMS

This report highlights the need for clear and comprehensive data about the population that is served by VR&E. Without such data, as well as research, we will not be able to project who the service-connected disabled veterans of the future will be, nor what their needs will be. Questions that should be addressed include:

Will their injuries and disabilities be considerably different than those of recent veterans?

Will the technology used on battlefields or in medical rehabilitation impact more significantly the veteran's future ability to be a productive member of civilian society?

How will medical advances, as projected by the Institute of Medicine or the National Institutes of Health, impact the VR&E program?

The Task Force's analysis of types of disabilities of veterans entering the VR&E program found that the number of veterans determined disabled due to neuropsychiatric illnesses is increasing. The increase in mental conditions is also being seen by other public benefit programs such as Social Security Disability Insurance. It appears that the majority of veterans in the Independent Living program are those with Post-Traumatic Stress Disorder (PTSD). Yet, as this report clearly states, Independent Living status within the VR&E program should not be the sole response to their needs. An assessment of the impact of an increased number of mental health disabilities on the VR&E services should be conducted as soon as possible. The outcome will likely conclude that new programs should be developed jointly with VHA to address the needs of these veterans. Of equal importance will be the development of a methodology that guides how VR&E interacts with VHA to plan for new solutions to disabling conditions.

IMPACT OF AN AGING VETERAN POPULATION ON SERVICES

Every social services delivery policymaker is well aware of the general aging of the population. The question should be raised as to the expected impact of the graying of veterans upon VR&E. Issues such as the aging of the general workforce could mean less discrimination against older veterans in the workplace and therefore more older applicants for VR&E services. As veterans age, many are filing additional claims for disability compensation, and many may initiate or renew their requests for VR&E services. VR&E should be proactive in addressing at least the following questions: Should

VR&E accept all disabled veterans regardless of age? Is age a criterion for prioritization of expected services? How should VR&E balance its resources vis-a-vis age of applicant and number of times services have been requested?

IMPACT OF DISABILITY DETERMINATION

The VA disability benefits adjudication system has been the subject of discussion and controversy for many years. Congress recently established, as part of the 2004 Defense Authorization Act, the Veterans' Disability Benefits Commission to study the compensation benefit structure and complete a report in 2005. They are directed to examine the appropriateness of such benefits and the appropriate benefit determination standards, compare veterans' benefits with other public and private sector disability benefits and, perhaps most important, "consult with Institute of Medicine of National Academy of Sciences with respect to medical aspects of contemporary disability compensation policies."

Ideally the Commission's deliberations will provide a framework for many policy decisions related to the VA's disability criteria that will be updated to reflect the current state of science, medicine, technology, and labor market conditions. Such recommendations could be the catalyst that moves veterans' disability policy toward use of scientific advances and incorporates economic and social changes that have already redefined the relationship between impairments and the ability to work within the private sector. Such discussion and modern approaches could significantly impact the workload and processes of VR&E.

For example, currently there are nearly 175,000 veterans with a 60 percent or more disability rating who have applied and receive a determination that they are "Individually Unemployable." The designation of "Individually Unemployable" entitles the veteran to a 100 percent rating with commensurate compensation. Yet the adjudication process never includes the views of a vocational rehabilitation counselor as to whether or not the beneficiary could participate in the labor force or whether a strong vocational rehabilitation or counseling program would be effective in assisting the veteran achieve employment, perhaps using assistive technology or other types of supports. The questions that are raised are: Without input into the IU determination process from a trained rehabilitation expert, should IU veterans or those applying for IU status be served by the VR&E program? How can an individual be officially designated "unemployable" (a label that should be an anathema) and allowed to participate in an employment program at the expense of another veteran who wants and needs a job?

It is recognized that over the years, the Congress and the courts have expanded the scope and complexity of veterans' disability benefits. It is hoped that the Commission will conduct a thorough review of the benefits schedule and challenge the status quo. They might begin by asking how a tender scar, migraine, or mild asthma can be the sole "disability" for which a veteran receives compensation according to a rating schedule and is thereby automatically eligible for VR&E services, in the same manner as a severely-disabled veteran.

THE GI BILL FOR THE FUTURE

The Task Force learned that more than 75 percent of those who enter the VR&E program proceed through a rehabilitation plan that includes a goal of a college degree. Though the data is not clear, one can assume (given the number of discontinued and interrupted participants) that most veterans spend far more than 4 years attaining their

degree. Equally important, most of these "students" never exhausted their GI Bill benefits. One assumes that is because the VR&E education benefits are considerably more generous than the current GI Bill. This pattern raises some questions: Does this mean that deficiencies exist in the current GI Bill? Or are veterans with disabilities just looking for the best deal? Should there be changes in the GI Bill that might make it more appealing to veterans with disabilities? What should they be?

In 1998, the then Vocational Rehabilitation and Counseling Program wrote a strategic management document that addressed the reasons that the program desperately needed to change in order to provide effective services to disabled veterans. The reasons for change were:

Inadequate focus on employment, Customer perceptions and expectations are out-of-step with the program's intent,

Inability to monitor outcomes and provide feedback to the program; Inadequate IT support for the program,

Inadequate access for veterans, Inadequate coalitions with peer organizations and partners, and inefficient business processes.

Despite such introspection, not much has changed. This 2004 Task Force Report not only urges management to rebuild the VR&E program but also provides a clear road map as to how to accomplish the objective. There is no excuse for lack of success.

THE CHARGE

Unfortunately, there are not as many successful social service delivery programs as one would like. Positive outcomes for adults, as measured by an individual's independence and employment, are often difficult to attain. But I believe the mighty band of nearly 1,000 VR&E staff has the resourcefulness and dedication to build a new service delivery system for veterans with service-connected disabilities. With leadership, appropriate resources, a broad and creative approach, and what I term "cheerleading support," they can reinvent themselves, they can get energized, and they can be the best program serving the 21st century rehabilitation and employment program—and just in time for those 21st Century service veteran. VR&E can become the model public sector members returning from Iraq, Afghanistan, or anywhere else in the world where freedom calls.

It has been a privilege to chair this Task Force and present our report.

Dorcas R. Hardy, Chairman, VA Vocational Rehabilitation and Employment Task Force.

THE MEDICAID AND CHIP SAFETY NET PRESERVATION ACT OF 2004

HON. JOHN D. DINGELL

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 22, 2004

Mr. DINGELL. Mr. Speaker, along with Representatives BROWN, WAXMAN, and CAPP, I am introducing the "Medicaid and CHIP Safety Net Preservation Act of 2004." This bill seeks to reaffirm the protections in the Medicaid statute for beneficiaries who receive health coverage through Medicaid in a waiver program. The Medicaid program currently covers more than 50 million Americans of all backgrounds, from pregnant women and children, to the working disabled and elderly in nursing homes. Recent actions by the Administration have raised concerns that the core principles