STATEMENT OF
JACQUELINE GARICK, ACSW, CSW, CTS
DEPUTY DIRECTOR, HEALTH CARE
NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
TO THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
ON
PRESCRIPTION DRUGS

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Mr. Chairman and Members of the Committee:

The American Legion appreciates the opportunity to provide its insights and experiences in dealing with the VA formulary and the prescription drug benefit provided.

The scientific advances in medicine have been miraculous! People are living healthier and longer lives due to the availability of technology and science. Screening and testing allows physicians to identify illnesses and diseases in their early stages and treatment protocols are becoming more sophisticated and targeted. Disease, pain, complications, side effects, and death are being mitigated. Medication continues to play a vital role in these advancements. The availability of pharmaceutical products, however, has become a major focus of debate. Issues range from ethical considerations, cost, demand, and availability. VA has not been immune, especially about its formulary and prescribing practices.

Last year, the Institute of Medicine (IOM) released a study, *Description and Analysis of the VA National Formulary*, to capture the challenges VA, the single largest purchaser of pharmaceuticals in America, faces as it attempts to optimize its approach in providing quality care to veterans. The American Legion applauds the breadth and depth of this analysis and shares concerns over restrictiveness, therapeutic interchange and generic substitutions, physician satisfaction and patient compliance.

The American Legion clearly understands the need for a formulary. Formularies offer pharmacological evidence-based treatment guidelines in conjunction with the ability to negotiate price using its leverage to drive market share. Formularies are commonplace in today's healthcare market. Managed care organizations, private hospitals and state Medicaid programs all rely on them. There is documentation that VA has relied on a formulary process since 1955. However, with the advent of the Veterans Integrated Service Networks (VISNs) and the Veterans Equitable Resource Allocation (VERA) methodology, the issue of pharmaceutical management has received heightened attention.

Veterans are very concerned about their access to pharmaceuticals and the quality of life they know they can attain through medication management. The IOM stated that only 0.4 percent of veterans complained about access to medication (based on data from patient advocates and the Veterans of Foreign Wars.) However, in a recent American Legion VA Local User Evaluation (VALUE) survey, it found that veterans were concerned about pharmaceutical access 88 percent of the time.

The greatest impact on the VA formulary system has been the fixed budget appropriation from Congress. It has forced VA to become more cost efficient and make more budget-driven decisions across the board. In its attempt to reduce duplication, streamline operations and cut costs, The American Legion believes that, in some areas, VA has gone too far. VA had estimated its FY 2000 pharmaceutical budget to be 15 percent. However, only 12 percent was spent nationally, with some VISN's significantly less than that (about nine percent).

Pharmaceutical purchasing and Hepatitis C Virus are the only two areas in which VA under spent from its projected budget. In spite of the fact that pharmaceutical prices are rising and research is costly, VA spent less money on treating veterans with medication than it could have done. The American Legion attributes this to the restrictive nature of the formulary and the complicated procedure to use non-formulary medications.

Although IOM's report concluded "The VA National Formulary is not overly restrictive." (IOM, 2000) The report did make several recommendations for changes, which included increased monitoring of generic substitutions and therapeutic interchanges, improve timeliness in adding newly approved FDA drugs to the formulary, improve non-formulary processes, provide education on formulary practices to veterans, and to continue the formulary based on quality practices and cost efficiency. The American Legion supports these recommendations, however believes IOM did not fully consider some of the problems associated with the formulary, and several other problem areas were not discussed in this report.

First, The American Legion notes that not enough attention was given to the off formulary process. During its site visits to VA facilities, physicians who report on the punitive nature and fear of poor performance evaluations they will get if they go off formulary too often confront The American Legion. Contrary to the position of VA Central Office, physicians do not feel free to use their best judgment in prescribing medication for their patients. The American Legion hears this complaint from providers all across the VA system and believes it is an unintended consequence of the non-formulary process. In addition, physicians describe this process as complicated and time consuming, which acts as a disincentive to do it.

In recent months, The American Legion has been involved with a serious discussion over an algorithm from VISN 22 (Law, Magcale 2001) that calls for patients to "fail first' with a "documented adverse event" on an anti-psychotic medication before the next drug in that class can be used. The American Legion strongly holds that physicians must be able to prescribe medication that is in the best interest of their patients

without the fear of poor performance evaluations and disciplinary actions. Doctors, in a working relationship with their patients are the best and most cost efficient treatment asset the VA has. Properly trained and well supported, physicians and other providers make decisions in the best interest of the patient and should not be second-guessed by administrators and financial officers. "Getting it right the first time" is truly the best approach to medicine. Restrictions that require patients to fail are immoral and inhumane. The American Legion recognizes that these pharmaceuticals can be expensive, but are not nearly as expensive as prolonged inpatient stays, incarceration, or rehabilitation can be. The American Legion is aware that the House VA, HUD and Independent Agencies appropriations bill for FY 2002 calls for VA to "immediately suspend the fail first policy as applied to anti-psychotic medications" and is grateful to the committee for its intervention. The American Legion hopes that this directive will be applied to all drug classes and not just to the anti-psychotics.

The American Legion is also concerned about VA's use of generic substitutions and therapeutic interchanges. Although IOM does conclude that these practices are acceptable, it does note that "pharmaceutical equivalents may not always have the same therapeutic effect or safety profile." Other factors, such as compounding technology, bioavailability, and patient acceptance or compliance, may be important." (IOM 2000) Although the generic drugs are more economical, they are not as widely available as the brand name drugs (only about half of the brand name drugs have a generic version).

The greater concern, here, however is that the substitutes, as IOM points out, may not be as effective or safe. Medication that does not work costs more in the long run and results in additional clinic visits, testing, and hospitalization, not to mention the pain and suffering the veteran experiences. The American Legion strongly recommends that the efficacy and safety profiles of these drugs be a higher weighted criterion for selection than simple up front cost. The ultimate cost of ineffectiveness and adverse events are too high a price for the veteran to pay.

The American Legion views therapeutic interchanges in the same light as generic substitutions. Veterans should not be subject to changes in their prescriptions each year when VA renegotiates contracts with the pharmaceutical companies. Patients, whose condition has become stabilized, should not be forced to change medication it in order for VA to save money. This can result in non-compliance or compliance confusion, adverse events, and/or negative side effects for the veteran. For the most part, the VA patient has a more complex medical profile than does the patient enrolled in managed care in the private sector and can not be equally compared. Therapeutic interchanges do not contain the same, chemically identical, active ingredients and the American Medical Association (AMA) describes them as "not pharmaceutical equivalents." (AMA, 1997) This difference in a complex and frail patient who is already on multiple medications and receives various treatments increases the patient's risk for treatment failure.

A secondary issue to therapeutic interchanges is, *how they are being made*? IOM finds that "therapeutic interchanges usually means that a specific prescriber approval exists before dispensing except in settings where exchange according to a collaborative

practice agreement or a preapproved policy and protocol is practical and has been accepted by prescribers." The American Legion has not found this to always be the case and that there can be confusion between the prescriber, the pharmacy and the patient. In focus groups conducted by The American Legion, a primary complaint from patients is that they get a prescription from their provider that they then take to the pharmacy, which will not fill the prescription because it is not on the formulary or they get a different drug. If they complain to the pharmacist, they are sent back to the clinic to discuss it with the prescriber, who by now, is seeing another patient. If they wait, the prescriber will change the prescription or contact the pharmacy on behalf of the patient and then will send the veteran back to the pharmacy. At any point in this frustrating scenario, the ailing veteran will feel too dejected and angered to continue and will depart the VA with no medication, returning when symptoms have worsened. The veteran is labeled as non-compliant and not seen as a candidate for newer treatment or research protocols.

IOM's report and VA leadership consistently recommends those issues surrounding patient's compliance and physician expertise is inherent in the education and training provided. The American Legion is a strong proponent of this concept and is in the process of launching its own patient and provider educational series, which is its *Teamed for Health* Campaign. This initiative will bring together the Department of Health and Human Services, (HHS) VA and industry to produce educational materials that The American Legion can distribute to its membership, VA users, and Medicare beneficiaries to improve the health status of those patients. Provider information will also be included in this initiative in order to keep physicians up to date on the latest research and treatment protocols. The American Legion sees this effort as a means of improving patient compliance and assisting in medication management, while improving best practice trends in VA and with HHS providers.

In another related matter, The American Legion has concerns over VA's Consolidated Mail Out Pharmacy (CMOP) system. Since 1999, CMOP service has been available nationwide to VHA's 22 VISNs. The program is currently running at maximum capacity with an estimated 61.3 million prescriptions annually. This production level has reached or exceeded the workload design of each of the CMOP facilities. Consequently, there are significant physical plant issues within the system. A prime example of this is the CMOP located at the Greater Los Angles Health Care System (GLAHCS). Established in a retrofitted warehouse on the grounds of the Brentwood Campus, annual production was originally designed at the level of 2.5 million prescriptions. In 2000, production was increased to 4.5 million prescriptions.

However, the building is poorly configured, limiting the capacity and efficiency of the operation. Additionally, the equipment frequently breakdowns, and the first-generation automated system (installed in 1994) is currently so old that parts are hard to get. The newest generation of dispensing equipment could nearly double the ratio of prescriptions dispensed to patients per worker. Clearly, new space and equipment are needed.

Overall, CMOP's program has no ability to respond to emergent need. Moreover, CMOP lacks the capacity to meet projected increases in workloads for FY 2002. There is no capacity for initiatives with other federal agencies beyond limited pilots. Solutions include:

- Expanding space and equipment at five CMOPs to new standard models.
- Replacing the two oldest CMOPs .
- Constructing additional CMOP facilities.

These are essential initiatives if CMOP's system hopes to be effective in its crucial role in the delivery of pharmaceutical services to America's veterans and their dependents.

In conclusion, The American Legion believes VA under spent on its pharmaceutical purchases as a result of a budget-driven philosophy that is clouding the intention of a formulary and is not always allowing for best practices to prevail. Restrictions, substitutions and interchanges need to be better monitored and carefully accounted for when utilized. Well-educated and well-supported providers are key to successful treatment and their clinical expertise and judgment should drive prescription practices for their patient population. Each veteran must be assured that they are getting the best possible care that not only the VA has to offer, but that the industry overall has available.

Mr. Chairman and Members of the Committee The American Legion is again grateful for this opportunity to present to you its experiences, and other comments in the intricacies of medication management within VA and concludes its statement.