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After reviewing the IOM's analyses and relevant scientific studies, and consulting with medical and legal experts in VA, I determined that the evidence concerning b-cell leukemia's, Parkinson's disease, and ischemic heart disease met the "positive association" standard of the Agent Orange Act. Accordingly, VA proposed regulations to establish presumptions of service connection for those diseases. The evidence regarding hypertension was less compelling and, in my view, did not establish a positive association under the statute.

The impact of other known causes and risk factors for ischemic heart disease is relevant in interpreting the results of scientific studies concerning that disease. In determining whether a study provides evidence for an association between herbicide exposure and a particular disease, IOM routinely evaluates the extent to which the study controlled for other known risk factors for that disease in order to minimize or rule out the possibility that an increased prevalence in the study population may be due to factors other than herbicide exposure.

By considering this factor, IOM is able to draw conclusions regarding how strongly the evidence shows that an association between herbicide exposure and a disease exists, independent of other known risk factors. In reviewing the IOM reports, VA also takes this factor into account in determining whether, and to what extent, a study provides evidence for an association between herbicide exposure and the disease independent of other risk factors. Studies that do not adequately control for other risk factors are generally less reliable than those that do.

Taking into account the number of statistically significant findings, the strong evidence of dose-response relationship, and the extent to which the studies controlled for risk factors including age, the evidence for an association between herbicide exposure and ischemic heart disease satisfies the "positive association" standard of the Agent Orange Act. The statute therefore directed that I establish a presumption of service connection, without regard to other independent risk factors.

Presumptions established pursuant to the Agent Orange Act of 1991

Written by By Carolie Watkins Guest Columnist
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VA's Office of General Counsel advised that the Agent Orange Act does not permit weight of the potential economic impact of my decision to establish a presumption under that statute. The statute requires establishment of a presumption if the "positive association" standard is met, and it provides that the standard will be met if the credible scientific and medical evidence for an association is equal to or outweighs the credible scientific evidence against an association.

Additionally, the statute does not permit VA to exclude a disease from consideration on the basis that it is a common disease. Rather, it directs VA to determine whether a positive association exists for each disease discussed in the IOM reports it receives.

A significant portion of the costs associated with the new presumptions is the result of a series of Federal court decisions in the Nehmer class-action litigation. In that case, the United States Court of Appeals for the Ninth Circuit has held that, each time VA establishes a new presumption under the Agent Orange Act, it must make retroactive payments based on claims filed as early as 1985.

This ruling overrides statutes expressly prohibiting retroactive payments based on such new presumptions, and it thus substantially increases the costs associated with presumptions under the Agent Orange Act. Under the Nehmer decisions, this requirement for retroactive payment will continue to apply to any future presumptions established before the Agent Orange Act's 2015 sunset date or any later date that may be established by future extensions of the act.