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The Curious Path of Pharmacovigilance

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Most advances in technology come from a traditional pathway of basic research performed in university laboratories or in governmental institutions. That is generally followed by commercial laboratories in the private sector taking over the basic science research and conducting applied research to make the goods or services of value to the individual or organizational consumer. Such private sector Research and Development (R and D) is often a lot more Development than research. After a new potential drug product active ingredient is synthesized in a university laboratory, the industry takes over in determining the correct adult dosage, and develops a formulation that is optimal for the typical patient. Then the pharmaceutical firm conducts the required clinical trials, the registration submission, arranges for manufacture, staff training, physician education and overall marketing, promotion and sales.

The unique nature of pharmacovigilance does not fit into that model at all. Pharmaceutical manufacturers are required by FDA regulations as well as an ethical code to report unlisted adverse events after marketing authorization has been granted. This post-marketing surveillance, also called Phase IV surveillance, has been improved and refined over the years, and the resultant field is known to us as pharmacovigilance. It has its own body of knowledge, publications of books, and journals, such as this one, professional society, its own vocabulary and innovations. It has been fascinating to watch the growth of pharmacovigilance through its infancy, into its adolescence and now into full adulthood.

Now we read about signal detection, pattern analysis, and other terms that will be 3 added to over time. But the major feature differentiating pharmacovigilance from most other disciplines is that it developed within the pharmaceutical and biotechnology industries. Subsequently, universities want to teach students about this field, but there are few professors who are experienced and highly skilled in the area. So, it can be seen as a discipline that went from the applied area to the theoretical. Industry experts will need to be recruited to help pharmacy schools teach their students about this new and exciting field that holds the promise of increasing effectiveness and reducing the incidence of trauma and expense of adverse events.

Surely, as the discipline is further accepted at private sector firms and as they add to their headcounts in pharmacovigilance, there will be a short-term scarcity of prepared personnel. When courses are developed and master's degrees specialization is recognized, there will be a fruitful area for employment in a field that is likely to do a great deal of good.

As this writer contemplates such a program, it is likely to have a combination of statistics, demographics, health information technology, toxicology or drug safety, along with an introduction to electronic medical records and experience in handling and interpreting large data bases. If pharmacists or physicians elect to specialize in this realm, they would not have to have further study in pharmacotherapeutics or toxicology, but that would be necessary for others entering the field.

It is exciting to be able to witness important events in the progress of science and one such event is this growth and acceptance of pharmacovigilance as a new area of specialization.

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