The concept of Residual Risk (RR) for plasma donations was discussed in the Winter 2012 issue of *Source*. However, Residual Risk has different interpretations when applied to blood donations vs. plasma donations and there have been questions on its meaning. Here we address the questions but refer the reader to the 2012 article for discussion of the methodology.

Addressing the Questions OF RESIDUAL RISK

BY GEORGE SCHREIBER, SC.D.

Basically RR is just what the name implies; left over risk after all health and test screening and other safety steps are taken. We know that donor health and laboratory screening do not interdict all donors with risk, however. In spite of the high levels of sensitivity in methods used for screening blood and plasma, false negative results may occur because screening tests are unable to detect the infection until a donor's blood or plasma reaches a certain level of analyte detectability. This period between infectiousness and detection is referred to as the infectious window period. The presence of certain viruses in asymptomatic donors who are negative on the screening tests (window period donations) constitutes the major risk of transmission of viruses in blood and plasma products. The RR is then the chance or probability of having a window period infection.
To put this risk in some fantasy life context, as pointed out in the prior Source article; the chance of being killed by an asteroid impact in a lifetime is about the same magnitude as having an infectious unit released for manufacturing.
manufacturing. The low residual risk reflects the impact of measures industry has taken to maximize plasma safety. This low risk coupled with the critical and highly effective removal and viral inactivation ensure the safety of plasma protein therapeutic products. Industry’s monitoring of Residual Risk of viral infection is an important quality control measure. Deviations from the trends can be detected and if required mitigating strategies considered. A perfect example is the case of HCV where U.S. incidence rates have shown an increase from 2010-2012. We can track industry data to see if this translates into increases in the residual risk estimates for source plasma. As seen in Figure 1, an increase in residual risk of about 25% has been observed for the same period. This is substantially less than the increase seen in population incidence rates, but indicates the need to carefully monitor risk trends.

Risk analysis is a valuable tool in the armamentarium of the plasma industry to help ensure that patients are protected against transmission of viral infection from their plasma derived therapies. Transparency in disseminating monitoring data allows patient groups and regulators to evaluate changes in risk in the donor population.

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Sources: