



## President's Message

Jerry  
Singleterry

The “tip of the spear”, the Navy considers the elite forces of the Navy Seals as this tip. They are the first to be sent into enemy territory to pave the way for the rest of the forces. I know this saying sound a little like militaristic verbiage. However this idiom can translate easily into the any situation. The main meaning is that we are the first to enter or move into that situation. This moving forward or first to enter, can it be related to how brave are or how gullible we are? I would say neither, because if you are reading this you belong to an elite group of professionals who care deeply for the laboratory, the ASCLS. This means you do not stand alone, especially if you are part of the ASCLS. It is state in the organization’s mission “is to make a positive impact in health care through leadership that will assure excellence in the practice of laboratory medicine.”

The ASCLS is the tip of the spear, a relatable concept when you look at all that we do as a group and as a member. The single member, a very important part of the team, who willing pays their dues. To which they know they are making a difference through numbers. This single member combined with others become a force to be reckoned with. There is always safety in numbers, and we laboratorians do stand together to attain the excellence in the practice of laboratory medicine.

The Legislative Day is prime example of how the ASCLS is entering into a situation, and taking a stance. The talking points for 2019 Legislative Symposium: Workforce Legislation Update to Title VII – monies from Medicare to clinical sites, Health Professions Student Loan Programs; PAMA – Protecting Access to Medicare Act, not a big focus this year but still on our radar; and the VALID act - Verifying Accurate, Leading-edge IVCT Development (FDA sees the need for unified approach to the regulation of in vitro clinical tests to protect patient safety, support innovation). These issues will be discussed in detail, and the group after being educated will meet with their respective representatives. From all across the country the ASCLS members will take this issues to Congress. We will speak with our House of Representatives and the Senators to let our voices be heard.



We as a group, entering first, become the tip of the spear. Please take the time to visit the web-sites:

<https://www.ascls.org/> or  
<https://members.ascls.org/index.asp>  
to learn more.

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# Medical Laboratory Professionals Week

## Now is the Time to Plan!



This year's MLPW is April 21 through 27.

ASCLS has a variety of resource to help you plan and celebrate our profession. These include a comprehensive guide, an online store, and much more. Please visit the site now and make your MLPW a success!

<https://www.ascls.org/participate/lab-week-mlpw>



**American  
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Clinical  
Laboratory  
Science  
Michigan**

### ASCLS-Michigan *Newslinks*

A bi-monthly publication of the American Society for Clinical Laboratory Science - Michigan. Deadlines for articles are the 20th of Feb, Apr, Jun, Aug, Oct, & Dec. Articles must have name of author. Anonymous letters will not be published. The editor reserves the right to edit all materials submitted for publication. Articles appearing in *Newslinks* represent the opinion of the author and may not represent the opinion of the society.

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for a complete listing and contact information for all ASCLS-MI board members and a wealth of other information on the Society.

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# Clinical Laboratory Science

A focus on what is happening in our profession

Featuring articles from Scientific Assembly Chairs.

Materials from all members are also welcomed. Submit to editor. See page 2 for details.



## Finally – the Solution to Neutralizing F-VIII Inhibitors in Hemophilia Patients?

Lynne Williams, Hematology/Hemostasis Scientific Assembly

Hemophilia A is a hemorrhagic disorder due to mutations of the gene for the clotting factor Factor VIII (FVIII). In the most severe form (<1% F-VIII activity) affected individuals suffer multiple bleeding episodes into joints and other tissues leading to crippling arthropathies and internal organ hemorrhage unless treated with F-VIII replacement products.

F-VIII replacement therapy can be administered either therapeutically to staunch an acute bleeding episode, or prophylactically to prevent acute bleeding episodes. However, in severe hemophilia, when very little or no F-VIII protein is made, the “foreignness” of replacement therapy can result in the formation of antibodies against the replacement product, called “inhibitors”. When a severe hemophiliac has made such inhibitors, the antibody inhibitors will neutralize the coagulant function of the administered F-VIII replacement product, rendering effective therapy problematic. A number of approaches to circumvent the problem of F-VIII inhibitors have been used over the years, with varying degrees of success.

Recently an alternative approach to treating hemophilia patients has been introduced and is generating a lot of excitement in the hemophilia community. Rather than utilizing replacement F-VIII product therapy, researchers and clinicians have devel-

oped a way to bypass the need for F-VIII in forming the complex which activates Factor X. Normally, F-VIIIa functions as a cofactor for activated F-IXa, facilitating the formation of a complex between F-IXa and F-X in the presence of phospholipids and  $Ca^{++}$ .

The drug Emicizumab is a bispecific antibody that has been designed to crosslink activated F-IXa and F-X, forming the complex needed to activate F-X even in the absence of F-VIII.

Bispecific antibodies are engineered monoclonal IgG antibodies that can simultaneously bind two different and unique antigens. For Emicizumab, one antigen binding site recognizes and binds activated F-IXa and the other binds F-X. By binding the two proteins at the same time, they are spatially positioned in the same way as does F-VIIIa, thus promoting F-IXa-catalyzed F-X activation. This ingenious way of circumventing the need for F-VIIIa in the activation of F-X in the coagulation pathway is unaffected by the presence of F-VIIIa inhibitors, as the bispecific antibody is not neutralized by these inhibitors. The bispecific antibodies have a low degree of immunogenicity, and patients do not form inhibitors to them. They also have long plasma half-lives (2-3 weeks) which enables weekly or biweekly injections (compared to several times a week injections of F-VIII replacement product).

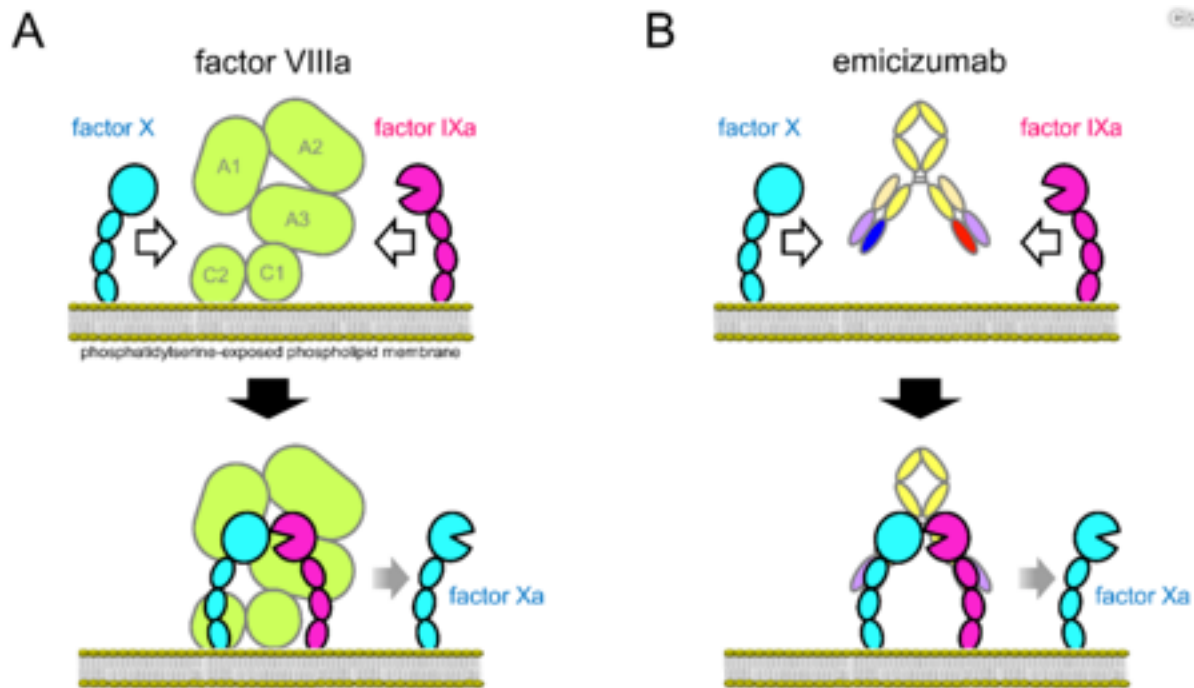


Image "A" Shows the normal function of F-VIIIa in activating F-X

Image "B" Shows the action of the drug Emicizumab

**Schematic Illustrations of the Action of FVIIIa and Emicizumab as a Cofactor Promoting the Interaction between FIXa and FX.**

Editor's Note: Graphic source: Supplement to Reference Number 2: <http://www.nejm.org/doi/suppl/10...>

A number of clinical trials have demonstrated the safety and efficacy of Emicizumab in treating severe bleeding episodes in Hemophilia A patients with inhibitors, as well as use for prophylactic prevention of bleeding in Hemophilia A patients both with and without inhibitors. In fact, the bleeding rate in these patients was significantly lower than the rate with previous F-VIII prophylaxis.

This new treatment approach appears to solve a major clinical complication for that subgroup of Hemophilia A patients who have formed inhibitors, as well as being a potentially more effective and efficient treatment option for all Hemophilia A patients.

**References**

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APRIL 10 - 12, 2019  
KELLOGG CENTER  
EAST LANSING, MI



## ASCLS-MI Conference Is Newly Designed For 2019!

- The Opening Keynote on Wednesday is at 11:30 am, making later morning arrival easier for most attendees to the Kellogg Center in East Lansing, Michigan. The first day's program continues after dinner in the evening with the Lifetime Achievement Award presentation to John Landis, MS, MT(ASCP) and Dr. Nadine Fydryszeski's presentation, "DCLS: Contributing Quality & Value in Delivery of Clinical Laboratory Services." So 6 CEUs are still available on Wednesday.
- Thursday continues with a second day of exhibits, a full schedule of educational sessions and our Celebration of the Profession Awards and Reception.
- This year, Friday begins with the Networking and Membership breakfast. Also new this year is a job fair allowing employers and prospective employees to meet.

Check out the full program of scientific sessions, exhibits, and other events at the ASCLS-MI website (<http://www.ascls-michigan.org/2019-meeting>)

OR visit the new CVENT registration site that also includes the program information (<http://www.cvent.com/events/2019-ascls-michigan-annual-conference/event-summary-c0866750936c4780908ff58e3e13306e.aspx>)



American Society for  
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MICHIGAN



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# ANNUAL CONFERENCE



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