OPINION

Guest Editorial

Toy Planes and Complicated Drugs

A toy plane has a handful of parts. A Boeing 747 has several million.

This makes sense. Toy planes are small, simple models, while 747s are large, high-performance aircraft. The model costs a few dollars because it's easy to manufacture. The 747 costs about $225 million due to its complexity.

This comparison is worth keeping in mind in the debate over "follow-on biologics." Biologics are today's most complex and cutting-edge medicines for treating diseases like cancer and multiple sclerosis.

Follow-on biologics are inexact copies of these drugs.

Congress is considering legislation that would allow the sale of follow-on biologics without requiring extensive testing -- essentially treating follow-ons like traditional generic drugs.

Unfortunately, confusing a "generic" with a "follow-on" is like confusing a 747 with a model airplane.

Here's why: Most drugs we're familiar with are "small-molecule" drugs. Aspirin, for example, is composed of just 21 atoms. So they are easily manufactured and can be identically copied by generic drug manufacturers. Since the generic forms are identical to their brand-name predecessors, they don't need their own safety tests.

Biologics, on the other hand, are complex, much larger compounds made from living organisms. Heroapin, for instance, a widely-used cancer drug, is composed of 25,000 atoms.

This size, and the variation of living cells making the drug, makes biologics impossible to copy exactly. That's why follow-on biologics can differ significantly from the original drug - and induce unpredictable adverse reactions.

For example, several years ago, a fully-tested biologic created here was licensed to be made in Europe using shared technology. But the European version resulted in patients suffering "pure red cell aplasia," where their bodies couldn't make red blood cells. Patients died, and many were permanently injured.

Today, even after 8 years of research, the cause of these reactions is still unknown.

The challenge for lawmakers is to create a policy that ensures that all follow-on biologics that enter the market are safe. Presently, the technology to map out the exact nature of one large biologic versus another is not available. That makes safety reviews inexact.

If biologics licensed from one company to another can produce adverse reactions, then follow-on forms that don't use shared technology should be of concern. In fact, recognizing this, the EU has developed a system of assessment that requires clinical testing before follow-ons are approved. The U.S. should do the same.

Congress should also work to support cutting-edge innovation in biotechnology. Since biologic drugs are so complex, it costs, on average, 50% more to develop a biologic than a conventional drug. As a result, it is extremely expensive to invest the time and capital to create new, breakthrough biologic drugs.

Thankfully, we already employ a method to provide incentives for this investment in the small molecule medicine world. It's called "data exclusivity." This is a legal mechanism that allows a company to keep the data associated with a drug's development confidential for several years. Data exclusivity has spurred small molecule drug innovation, and should be applied to biologic drugs as well.

U.S. policymakers should require relevant clinical data and testing to ensure safety of all follow-on biologics. And appropriate data exclusivity should be put in place to foster innovation.

If chemical drugs were toy planes, biologics would be 747s. We need to remember that when we consider what systems to employ to ensure follow on biologic safety.

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The Carlisle Mercury

The Carlisle Mercury (USPS 023-152) is published every Wednesday by The Carlisle Mercury, 218 Locust St, Carlisle, KY 40311.
Periodicals Postage Rates are paid at Carlisle, KY 40311.
POSTMASTER: Send address changes to The Carlisle Mercury, PO Box 272, Carlisle, KY 40311.

Member of Kentucky Press Association and The International Society of Weekly Newspaper Editors

2007 SUBSCRIPTION RATES: $25.00 for one year in Nicholas County, $30.00 elsewhere in Kentucky and $35.00 out of state. Subscriptions include sales tax where applicable. All subscriptions payable in advance.

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Carlisle, KY 40311
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Bond's Broadcast

Bond's Broadcast
By Hank Bond

Through the eyes of a child

Most of us can't remember what things looked like when we were little. I'm talking about nearly everything.

This past weekend Marilyn and I went to Falmouth, twice, to watch Evan play in a t-ball all-star tournament.

It was played at a municipal park in Falmouth, built in part by the Rotary Club, which has been maintained to the hilt.

As a side note to this, one of the umpires in the 9-year-old tournament was Lonnie Greg. Lonnie, a standout athlete at Pendleton County High School, and I refereed basketball games together for years, and he still works the hardwood and the diamond. I watch.

He caught my eye as I was waiting for Evan's game to start and we exchanged a couple minutes' conversation between innings of his game.

"I would have called this tournament if they had asked me to pay them," he said as he watched the pitcher warm-up for the next half-inning.

"This is real baseball," he said. "It's how they see it. It's fun, it's about playing a game with friends -- often against friends – but it's all about the love of the game."

He repeated he would have paid to have the opportunity to be there – and I was glad he was.

Lonnie is a purest and that's what made me think about this topic.

Seeing things as a child does – just as Lonnie does – life is about the fun it produces.

Lonnie is one of the hardest working guys I have ever known and is a true gentleman.

I find it refreshing to watch children and how they react to things.

The happiness of just getting to play brings a charge to so many of these children, at times I can see that parents – and grandparents for that matter – often take it all too seriously.

As most of you can imagine I get around to a lot of places and see a lot of things. Of late I have been trying to see things a little more through the eyes of a child.

Now that my children are all of age – you notice I didn't say grown up because they're a lot like their daddy – I can look back to the years we all gathered around that big 10-foot table and enjoyed a meal. The conversation was non-stop.

I watch children here at school. These young ones are only as good or bad as the product their parents produce. Especially when they are young.

It's pretty clear that a child is pretty much developed by the age of 5.

So if there's no reading or counting or looking at clock with hands – not digital numbers – then being ready for school may be suspect.

This brings me to what I saw at these t-ball games.

I saw parents scream at 6-year-olds for making a base running mistake. I saw parents claim they were cheated when a call didn't go their way, and I saw coaches stretch every rule hoping once in a while no one would catch them.

I also saw about 30 young boys, two teams at a time, with only two things on their minds. Half of them were worrying about somehow managing to hit the ball fair and get on base every time they batted. These players even had the hope they might score if the next batter could get a hit.

The other half, who were in the field, hoped that they could stop those grounders and oh, if luck would prevail, catch that pop fly.

I saw something in the championship game, which I might add was won by Evan's Fleming County team-that I have never seen in my life.

This would even include the professional level.

The pitcher for Evan's team made an unassisted, triple play.

He caught a pop-up, ran to first to tag the bag as the runner moved to second, and then spotting the runner going home raced him to the third base bag. The runner got there first but overran the base and the pitcher tagged him. Three outs.

If the opponent's coach hadn't tried to get an advantage by not sending a runner back from third to second as he was instructed to do, the triple play wouldn't have happened.

I just wonder what these little guys saw, looking through the eyes of child?

And so, for, another week, thanks and thirty.

Veloz Viewpoints

Veloz Viewpoints
By Amy Bond Veloz

The price of a good deal…

Greetings from Nevada! I hope you are all having a great week.

What does it take to get a good deal in today's society? Caring people who try to give to those who have less than they do? A little luck and a lot of stressing out and hard work? For my family this week it took both.

Ben and I have been talking for several months about possibly buying a new – to us- pick up truck. The truck he has had since college is a three-door truck, and while it has been good to us, for the most part, it just doesn't fit our family. The car seats fit in the back seat but my seat has to be so far forward that my knees hit the dashboard.

To our favor, gas prices are through the roof, therefore, many people are getting out of their trucks for smaller, more gas, efficient vehicles. We have been watching various ads sites for just the right truck and Saturday night I found it.

A Ford, F150 Lariat, fully loaded, two-wheel drive, 5.4 liter engine, 2005 with less than 45,000 miles on it. We had said all along that our range was around $12000, but for the right deal we could go a little bit higher.

So, I emailed the person selling it to say we were interested and that we wanted to come see it. After waiting nearly all day on Sunday for a response he said okay but we had to be there in an hour and a half. That didn't leave us much time to drop the kids off at the grandparents' house, so we just loaded them up and raced there.

Being a late Sunday afternoon we made great time thanks to very light traffic and we were even able to meet him a little early. We looked at it, Ben test drove it while I sat in our car with the babies asleep in the back and anxiously awaited his return.

He came back with this look on his face that I have only really seen a few times…I knew he wanted it. We told the guy we wanted it and he took an approach that kept us both from sleeping on Sunday night. He said, "I have a couple other people interested so whoever gets the money first gets the truck." This was a slight dilemma, as we had to get it financed and therefore knew we would be under the gun.

So, after getting very little sleep on Sunday night we were up at six Monday morning and left the house by seven to be in Vegas when the banks opened. We talked to our bank and thanks to starting the loan process over the phone we were conditionally approved pending proof of income and the vehicle vin number.

I called the seller to get the number and got what I felt like was good news. One of the other people interested bowed out because they didn't think they could get the financing so he wasn't going to show it again until 5 p.m., giving us time to get the financing.

We decided to go to our credit union and get paperwork going there to get financed since their interest rates are better. After spending about an hour there we were told it would take one to two days to finance, so we headed to our bank.

On the way over to the bank, he called to get a status on our financing as he had someone who wanted the truck and wanted it right now. Again, stress poured over both Ben and myself.

So, after two hours at the bank, going by the guy's house to drop off a deposit so he wouldn't sell it before we, could get the financing and a lot of knots in my stomach, we financed the truck and it belongs to us.

While we are both extremely excited to have this great, truck for about $6000 less than it is worth, the stress of the past few days has really worn on us, although, it was really worth it for Ben.

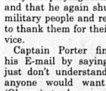
When we went to the buyer's house to look at extra tires and rims he had for the truck Ben got to see his Lamborghini and Ferrari that were parked in his garage. He also has motorcycles and seadoos and a Hummer, BMW and Honda.

To say the least, the guy gave us a great deal on the truck and for that we are very grateful. We would have been more grateful if we hadn't endured the stress of getting the financing. Oh well, all is well that ends well.

Until next week, make it a great one!

Amy

Talkin' From The Mountains



Talkin' From The Mountains
By Dale Greer

Captain Jeffrey S. Porter is a disgrace

I am a veteran of the United States Army and I believe strongly in supporting our troops, but there is a Military Officer serving in Iraq who has dishonored our Military and should be disciplined.

His name is Captain Jeffrey S. Porter stationed at TF Wasatch in Bagram, Afghanistan. He and his wife live in Charlottesville, Va. having moved there from Utah.

The Porters orchestrated a vicious, false, worldwide attack on Barrack Obama. The New York Daily news says Captain Porter has now contacted them and admitted his wrongdoing.

Many of you probably know about Captain Porter's E-mail already. You may have been a victim and received it. I counted 17 pages of reports about his Email on Google alone.

I don't have the space to print his entire Email here, but I will give you quotes and information from it.

Captain Porter insinuated that he was at Bagram, Afghanistan when Barrack Obama visited. His wife introduced the infamous E-mail and called it her husband's "first hand account."

Captain Porter said soldiers tried to shake Obama's hand and he "blew them off."

Captain Porter went on to say that Obama then went to a tent known as the Clam Shell so he could take a publicity shot playing basketball and that he again shunned military people and refused to thank them for their service.

Captain Porter finished his E-mail by saying: "I just don't understand how anyone would want him (Obama) to be our Commander-In-Chief. It was almost that he was scared to be around those that provide freedom for him and our great country."

Captain Porter signed off by saying, "If this is blunt and to the point I am sorry but I wanted you to know what kind of caliber of person he really is. What you see is all fake."

"CPT. Jeffrey S. Porter
Battle Captain
TF Wasatch
American Soldier

Who is "all fake" Captain Porter?

Obama didn't visit the Clam Shell or take any basketball publicity shots there. You and your wife passed your E-mail off as your "first hand account." Were you even there?

The U.S. Military in Afghanistan immediately labeled Captain Porter's E-mail false and said charges could be brought against Porter. The military praised Obama's availability to everyone during his trip to the Middle East.

The E-mail I received also mentioned the names Tiffany and Jeff Peters. I assume the name Peters was meant to be Porter. I mention that because sometimes the ploy is to keep a lie going under another name. There could be another round on its way into our E-mail inboxes.

The Army Times contacted Captain Porter, who the Times says is a Utah Army National Guard member assigned to the 142nd Military Intelligence Battalion. Porter declined to comment.

The Army Times also contacted his wife Tiffany who helped put the false E-mail out to the world. She admitted the E-mail had what she called "discrepancies," but according to the Army Times, she said she was "not at liberty" to say more.

You were at liberty to send the E-mail out to the entire world, Mrs. Porter. You, in fact, abused the liberty you are given by our great nation. Don't send out anything without verifying it.

Mrs. Porter could be a victim or an accomplice. Perhaps she thought she could trust her husband. If that's the case, she was wrong.

Mrs. Porter's part of the E-mail starts off: "I don't know each of your political convictions and apologize if anyone finds this offensive. I thought it was important enough to share. This is Jeff's first hand view of Senator Obama."

The New York Daily News says Porter's message to the paper recanting his widespread E-mail attack on Obama says in part:

"I am writing this to ask that you delete my E-mail and not forward it. After checking my sources, information that was put out in my E-mail was wrong.

This E-mail was meant only for my family."

Only for your family? You and your wife, sir, are responsible for vicious lies going out to potentially mil-

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OPINION

Steve's Report

Steve's Report
By Steve Scalf

On Friday, July 25th I reported to the Army Transition Center at Schofield Barracks and was released from active military duty. Although I am technically still in the service for a couple more months, I will be carried as "on transition leave" status, or what they used to call "terminal leave." I'm glad they changed the name; the old way sounds fatal.

Our last weekend in Hawaii, we naturally decided to go to the beach. We wanted to go "boogie boarding" one last time so we headed out to Bellows Air Force Station on the eastern shore. The waves are usually great there.

After a couple of hours of riding the waves, I traded in my boogie board for a pair of swim goggles and followed one of my traditions (or bad habits): Every time we go to the beach, I go for a long, solo swim out in the open ocean. Sometimes I'll be out there as long as an hour.

Not long after getting out past the shallower waters the surf action changes. There are still surges and swells, but the rhythm is different. As I clear my mind of everything else and focus on the "motion of the ocean" my swimming strokes begin to harmonize with the currents. Instead of fighting the swells I simply tread water holding my position and letting the water lift me. Then, as the wave passes I suddenly push forward quickly, using gravity and the downward slope of the water to help propel me.

It's almost hypnotic when my strokes synchronize completely with the ocean's rhythm. Before long, the swimming becomes almost automatic, freeing my mind to reflect on other things.

This time my thoughts drifted back to 1998, the last time we were about to leave Hawaii. Our last weekend, just like this time, we decided to go to the beach one more time, only that time we went to Waikiki.

Most of the time, the water at Waikiki is relatively calm, so for my solo swim I usually don my mask, fins, and snorkel, swim about a quarter mile out past the reef into the deep water and swim with all the beautiful, tropical fish. I frequently find sea turtles or rays out there, or have some other adventure to share when I get back.

When I got out past the reef, however, I was met by humungous waves 15-20 feet high. This made the water so murky that snorkeling was out of the question. So I decided to go body-surfing instead.

I swam out a good distance beyond the reef ducked through a few waves and then waited for a big one. There is a brief instant when a huge wave comes up from behind and starts heaving you in, lifting your legs higher than your head, when you think you're going to get tumbled. Frankly, it's a little terrifying. Higher and higher you go until you reach the very crest of the wave.

Then from that dizzying height there is an exhilarating burst of speed as the wave propels you forward converting your initial fear into thrills of excitement. It's better than any amusement park ride I've ever been on.

I would slide down the back of the wave just before it broke onto the reef and then head back out for another ride. I repeated this several times getting more comfortable each time. Except you can never allow yourself to get comfortable with the ocean – that's when bad things happen. You must always be on the lookout for the unexpected.

I had just finished riding one wave and was sliping down its back when I realized (too late) that it was "double-stacked" meaning there was another wave right behind it. Unprepared, I was sucked into the second wave's undertow. My mask was ripped from my face as I tumbled in the churning water until I didn't even know which way was up.

Eventually the bubbles in the water cleared somewhat and I could see light in one direction, telling me where the surface was. I swam to the top and gasped for air. Somehow I had managed to grab my mask, even though the strap was broken. As I tread water, I examined the mask to see if I could fix it. I should have been paying attention to the ocean instead.

Another huge wave caught me by surprise, sucking me up inside and tumbling me again, this time not only pulling the mask from my grip but tearing one of the fins off my feet. It dashed me onto the reef, shredding the skin on my belly and right thigh on the jagged coral.

My situation was critical. Without a mask, I wouldn't be able to find the safe channels through the reef. Without both fins, I didn't know if I would be able to swim fast enough to escape the waves. Time and time again as I worked my way back across the reef the swells drove me against another coral outcropping, adding to my rapidly growing collection of cuts and bruises. It took at least 10 minutes to finally clear the reef and another 20 minutes after that to finally reach the shore, bleeding, exhausted and shaken by the realization of how narrowly I had cheated death.

That memory of my last weekend in Hawaii was what my mind chose to replay as I was out on the open ocean, once again on my last weekend in Hawaii. Suddenly, my passion for solo swimming evaporated. I found myself looking around for sharks or other dangers, instead. I turned around and raced back to shore.

Surprised, Cindy remarked, "Wow! You didn't go out as far as you normally do!"

I don't know if I was covering my pride or simply telling the truth when I shook my head and replied:

"I went far enough."

Signing out from Honolulu
Stephen Scalf

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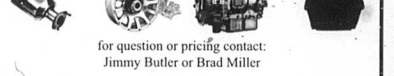

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4th District Report

4th District Report
By Geoff Davis
4th District Congressman

Housing Bailout Bill Hurts Kentuckians

Last week, Congress passed the most sweeping and potentially damaging housing legislation in a generation: the Foreclosure Prevention Act of 2008 (H.R. 3221). I joined 151 of my colleagues and voted against the bill because it will harm Kentucky taxpayers.

Over 95 percent of American homeowners are making their mortgage payments, often at significant sacrifice. It is unfair to force the vast majority of homeowners and renters to pay for bad decisions and risky financial deals made by irresponsible lenders and borrowers.

The bill will allow irresponsible lenders to hand off bad loans to the federal taxpayer through a new program run by the Federal Housing Administration. This program could refinance as much as $300 billion of the worst home loans out there today.

The bill also provides an unprecedented blank check to bail out Fannie Mae and Freddie Mac. Fannie and Freddie are Government Sponsored Enterprises (GSEs). GSEs are private corporations chartered by Congress to improve the credit markets. While they were intended to provide additional stability to the mortgage market, any potential failures were never intended to be the responsibility of the taxpayer.

Fannie and Freddie serve an important role in the mortgage market. Not only has their success contributed to the housing boom that we experienced over the past decade, the companies were also designed to absorb some of the shock of financial crises like the one the housing market is experiencing now. Fannie and Freddie currently hold about $5.2 trillion in mortgages. The non-partisan Congressional Budget Office estimated that bailing out Fannie and Freddie would cost at least $25 billion, with the potential to cost over $100 billion. Handing the Treasury Secretary a blank check of this magnitude without committee hearings, open debate and mandatory additional oversight is an abdication of Congressional responsibility.

As private corporations, this proposal would allow Fannie and Freddie to continue making and keeping profits private while nationalizing their risk. Instead of a bailout, I have consistently supported strong reform measures for the GSEs, including a more powerful regulator with the authority to implement stricter safety and soundness requirements.

While the housing market in the Fourth District does not compare to the downturn in California or Florida, we have seen

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PUBLIC NOTICE

The Nicholas County Fair Board's Building Oversight Committee will be accepting sealed bids for a post building 72' by 160' by 12'. Specifications for this building can be obtained at the Nicholas County Extension Office, 368 East Main, Carlisle, Kentucky. Office hours are 8 am thru 4:30 p.m. Bids can be submitted at the Nicholas County Extension Office August 11 thru the close of the business day August 22. The building is to be completed within 120 days from contract agreement. The committee reserves the right to refuse any and all bids.

Published in The Carlisle Mercury Wednesday, July 30, 2008

PTA everychild. onevoice.

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The Nicholas County Elementary-Middle School PTA has partnered with Kidz IDz to help parents enroll their children in the Kidz-IDz School ID Card Program. The cost is only $6.00 and the cards are invaluable in maintaining student safety and can make the difference in a missing or injured student being quickly identified and provided with the appropriate assistance.

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