# Conference Summary

## Pharmaceutical Executive Summit: Emerging Strategic and Financial Issues in the Pharmaceutical Industry

**October 23, 2024**
**In-Person and Virtual Conference from 11:45 am EST to 5 pm EST**
**Yale Club of New York City**

## Agenda

11:45 am **Luncheon Begins (in-person) and Virtual Networking**

12:15 pm **Welcoming Comments**

**Peter Young**, CEO and President, *Young & Partners*

12:20 pm **Keynote Speaker**

**Brave New World – Where Are We Heading?**
**Peter Marks, M.D., Ph.D.,** Director, Center for Biologics Evaluation and Research, *U.S. Food and Drug Administration*

12:50 p.m. **Fireside Chat – Latest Developments in Complex Biological Products**
**Peter Marks, M.D., Ph.D.**, Director, Center for Biologics Evaluation and Research, *U.S. Food and Drug Administration*

Moderator: **Dr. Stephen P. Spielberg**, MD PhD, Senior Adviser, *Young & Partners;* former Deputy Commissioner for Medical Products and Tobacco, *FDA*

1:10 pm **The Pharma and Biotech M&A and Financing Landscape**

**Peter Young**, CEO and President, *Young & Partners*

1:40 pm **The Pharmaceutical Market: Trends, Issues and Outlook**

**Doug Long**, Vice President, Industry Relations, *IQVIA*

2:30 pm **Virtual and In-Person Town Hall and Coffee Break**

3:00 pm **The Impact of Artificial Intelligence on the Creation of Medicines**
**Najat Khan**, Chief R&D Officer and Chief Commercial Officer, *Recursion Pharmaceuticals*, Former Chief Data Science Officer & Global Head, Strategy & Portfolio Organization, Innovative Medicine R&D, *Johnson & Johnson*

Moderator: **Fred Hassan**, Director, *Warburg Pincus*, Former CEO of *Schering Plough* and Former CEO of *Pharmacia*.

3:30 pm **The Changing Roles and Relationships - Biotech and Pharma**
**Michael Christel,** Group Managing Editor, Pharmaceutical Executive, Pharmaceutical Commerce and Applied Clinical Trials, *MJH Life Sciences*
**Sandy Zweifach**, President/Chief Business Officer, *IMIDomics, Inc.*

Moderator: **Peter Young**, CEO and President, *Young & Partners*

4:15 pm **Speakers Roundtable: What Does the Future Hold?**

**Michael Christel,** Group Managing Editor, Pharmaceutical Executive, Pharmaceutical Commerce and Applied Clinical Trials, *MJH Life Sciences*
**Fred Hassan**, Director, *Warburg Pincus*, Former CEO of *Schering Plough* and Former CEO of *Pharmacia*.
**Najat Khan**, Chief R&D Officer and Chief Commercial Officer, *Recursion*
**Doug Long**, Vice President, Industry Relations, *IQVIA*
**Peter Marks, M.D., Ph.D.**, Director, Center for Biologics Evaluation and Research, *U.S. Food and Drug Administration*
**Dr. Stephen P. Spielberg**, M.D. PhD, Senior Adviser, *Young & Partners;* former Deputy Commissioner for Medical Products and Tobacco, *U.S. Food and Drug Administration*
**Sandy Zweifach**, President/Chief Business Officer, *IMIDomics, Inc.*

Moderator: **Peter Young**, CEO and President, *Young & Partners*

5:00 pm **Conclusion of the Conference**

## Young & Partners

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**Brave New World: Where Are We Heading?**

**PETER MARKS, MD, PhD**
**DIRECTOR**
**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FDA**

Gene therapy is an interesting place right now because it is an area where there was a lot of investment originally starting in 2018, but there was a cooling off of interest as the pandemic wore on and a number of companies failed. There are two major ways of doing it right now, taking cells from somebody and ex vivo modifying those cells with gene therapy. Or alternatively, give them a gene therapy locally, either into the eye or systemically. The interest in genome editing and in vivo genome editing has also cooled off.

We have 19 products and 20 different brand names of those products that are approved for gene therapies. CAR-T cell development was something that has been developed over the past 15 years. The CAR-T paradigm has been addressed in two ways, in a centralized or decentralized method. I suspect in 5 or 10 years we will move past this to allogenetic CAR-T cells where you take cells from a healthy donor, use genetic technology to strip off the molecules that would normally cause rejection and then add in the genes you are looking to be recognized. The beauty of this is that you can have multiple targets instead of just one target. You will be able to make CAR-T cells with Boolean logic. The reason this is nice is because you can have a healthy donor where you can make 100 doses at a time and make this more cost effective. You can also expand these products into uses outside of oncology in areas such as autoimmune disease. The next step for these products may be getting rid of the manufacturing facility altogether for making the cells and instead just give a CRISPR construct in a lipid nanoparticle or a scaffold that targets the T cells and have in vivo CAR-T cells reducing the number of cells transduced.

There are an estimated 10,000 plus rare diseases that have to be addressed in some ways. It is very remarkable that CRISPR, first described in 2012, is now being used as part of an approved production process. First generation CRISPR was a nice molecule that allowed us to do genome editing. Amazingly at Stanford and MIT they have moved the technoloogy so much that you can have base editors so that you can fix a given base abnormaility. Or you can rewrite segments in the DNA or create phoning sites where long segments can be delivered. The biggest challenge with adeno associated viral vector gene therapy is the challenge related to making it at scale. It is a biologic process, with a producer cell line that is one in a million. Then you need to have the virus particles made where the virus partciles need to be full of the DNA vectors. Some people have gotten it and others claim they have gotten it. The FDA knows what companies are doing or not doing in terms of manufacturing compared to what they say publicly. I will also mention what we are doing at the FDA to fix the clinical development timelines and different global regulatory requirements. We are working to help advance manufacturing for gene therapies and how we can apply a platform approach. We are also trying to maximally use accelerated approval and reach some global regulatory convergence. One of the funny things about manufacturing is that a lot of the process can be automated but no one has spent the time or effort because that model is not a great business model. Although now, we are trying to and working with various grantees to think about a device type model for making the product. This would be a device with disposables and consumables to make small batch gene therapies.

It turns out right now, we make sponsors go back and do all the toxicology work and manufacturing information even though they may be the same for product 1, 2, 3 and so on. The Platform Technologies Act now allows us to designate something as a platform for an approved product where sponsors can come in with subsequent products using that same platform where they can modify it and just focus on the modicications. I think we will see a transformation 10 years down the line where CRISPR will be the workhorse of gene therapy. For example two different constructs can be 99.5% identical with the exception of a stretch of nucleotides. It will not be efficient to regulate 10,000 products in this way and it will be more reasonable to regulate this almost like a general tool and the device flow. You might have a genome editor that we approve for the variety of mutation that affect the liver in gene coding sequences or something similar. It will require some real advances in technology where we will require small scale, high throughput machines. But we know how to do this, as in the example of mRNA molecules.

We are also trying to do things to move the ecosystem faster. I have had stones thrown at me routinely for the use of accelerated approval. For many rare diseases and common diseases, it is very time consuming to get to a traditional endpoint. It is much easier to look at a biomarker change such as how somebody expresses hemoglobin that can reasonably predict future clinical outcomes. These are facilitated especialy by genetic technologies as you know the gene product that you need to replace and you can measure something upstream or downstream in that pathway. In kids who have diseases that progress over a number of years, you are able to intervene sooner by implementing the use of accelerated approval that can make a very big difference. As long as we get it right roughly 90% of the time, it is okay. What is nice about this is that we can look at animal models or human experiments. If we can replace that protein using gene therapy to the same level, it is reasonably likely to predict that they are going to have a clinical benefit.

Operation Warpspeed was able to make a vaccine in 11 months, which was a record time, through a lot efficiences, including regulatory efficiencies. One of the things that became apparent is that we and other high income country regulators were all doing the same thing and we realized there is no reason to be doing that. We are currently thinking that we can do this in a non-pandemic time as well and be able to streamline submission processes. This is particularly relevant for small market products, for example, if there are only 50 people in the United States that are potential candidates, the NPV calculation does not look good. If you add the EU and Asia, you suddenly start to have numbers that make an NPV calculation look more attractive, which could help in the rare disease space and all disease spaces. We know that it can work in the oncology setting because this was done with 8 or 9 countries for oncology products, and we are trying to do it now, with a pilot ongoing with the European Medicines Agency. Finally, we are trying to apply a process of giving a project manager's phone number and email to sponsors such that when they have a question they can just send the questions. The project manager at the FDA will farm them out to the CMC reviews, clinical reviews, etc. By doing this, we have resolved many questions more rapidly and saved manufactured wasted time. The cost of doing this process was extra people, but it wasn't an incredibly large number of extra people. We are piloting to start in the rare disease space. Initial feedback is that people like it a lot, but we will have to show whether this makes a difference. I hope this works because ultimately our goal is to try and help this ecosystem move rapidly forward. I think with genetic medicines, we're going to have to shift the paradigm with these platforms.

**Fireside Chat- Latest Developments in Complex Biological Products**

**PETER MARKS, MD, PhD**
**DIRECTOR**
**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FDA**

**DR. STEPHEN P. SPIELBERG**
**SENIOR ADVISOR, YOUNG & PARTNERS**
**FORMER DEPUTY COMMISSIONER FOR MEDICAL PRODUCTS,**
**FOOD AND DRUG ADMINISTRATION**

Spielberg: That was wonderful, Peter. We used to always sit around the table and discuss genetic diseases! When I think how rapidly things have changed in 60 years, what strikes me even more is hearing what you talked about today versus two years ago. The rate of celebration of concepts, the rate of acceleration of technologies, and the rate of integration of all of this into the regulatory process is utterly mind boggling. I am just blown away and very excited. From the point of view as a pediatrician who's taking care of a lot of kids, the rate of change is amazing.

Two general thoughts. One thought is how is this going to fit into our healthcare system? How are we going to care for patients in real time and also have the clinical resources for both hospital and outpatient? Second, how are we going to teach this in real time with the rates of change to the future generations of physicians so that they can be skilled practioners of molecular therapuetics? One question for you Peter, as you were talking about rare disease, it is not whether genes are present or absent, and whether they are correct or incorrect but how they are expressed over time. You are dealing with a developing and changing person and recognizing the difference between ages. Any comments on where the agency is with respect to this?

Marks: Thas is a great question. I think it comes down to having the rigth fit for specific therapes. For the older child, we're going to have to rely on some cellular therapy. I think it may turn out at a certain point even if you use gene therapy, it is not going to fix what really needs to be fixed. What you might be able to do though with cell-based therapy is to deal with some cardiac complications, or other complications, and at least prolonging life. I think it is kind of inescapable that increasingly understanding what someone's genetic defects are early in life may be really critical.

It used to be very expensive. If you have a whole genome sequence on your child or a partial sequenc, the cost is now in the hundreds of dollars. This may also be in areas where you have history, since the genome sequencing hit rate is a couple of percent. If you stack the deck by having the right historical context as well, it can improve. I think my answer to you is getting gene therapy early is good, sometimes later it is helpful, but it is not perfect. The cost, such as the one on the New York Times article yesterday, is not easy. Where you can intervene in vivo, has to be where we are headed cost effectively, because 50 to 100 years from now, we cannot have scalable cell based therapy.

Spielberg: That's a great perspective Peter, and you can see over the horizon where technology will fit the science. Talking with my colleagues, we also see the potential gaps of getting the understanding and the physical setups to provide this care. When I was at Boston Children's the wards were still designed to take care of iron lungs and were terribly designed to take care of kids with illness in real time then. I hope there will be a lot of opportunities to bring together NIL, FDA, industry and academia to talk about the exciting things that you have talked about so far.

Marks: The ARPA-H has a fair amount of money and has recruited someone who is quite visionary in this area. They realize you need to start with the actual diagnosis in the hospital and go all the way through to the delivery of the therapy. They are also dealing with the issue of reimbursement. One thing I have to offer that will make this all possible is the engineering of these things and how to make them cost effectively and efficiently. That's been an

area where we have lagged behind since our science is moving so rapidly. You have to remember it took a bunch of engineers to figure out how to miniaturize a cellphone and make it all happen. If we want to get to where I would like to see us in a decade, we are going to have to see people put in investment in developing the manufacturing technologies. Currently we just can't produce these products in a cost-effective way.

Spielberg: The first human genome costed billions and now we're down to a tiny fraction of that. I'm convinced that getting there will require a whole cadre of skilled engineers guided by the biological sciences and scientists, and clinicians. It will be interesting challenge for the FDA to figure out how to regulate manufacturing in a totally different way and I am delighted to hear some of the things that you've been doing to accelerate that process.

**The Pharma and Biotech M&A and Financing Landscape**

**PETER YOUNG**
**CEO, PRESIDENT AND MANAGING DIRECTOR**
**YOUNG & PARTNERS**

Business Conditions

There has been tremendous innovation in the industry. There has been also a changing relationship between biotech and pharma. The FDA has also increased the number of approvals over the years. There are a number of orphan products being developed and the vaccine development during COVID elevated the pharma industry's reputation. However, high prices of drug development and poor biotech public company valuations have negatively impacted the industry.

Stock Market

The biopharma industry has generally performed well in the stock market, particuarly for Big Pharma companies in the U.S. The European Big Pharma companies have not done so well. The generic pharmaceutical industry, after suffering from low share prices for many years, has experienced some improvement recently. The NBI Biotech index continues to underperform relative to the market.

The biotech industry did not do well. The NBI index increased by 7.0%, which is helpful, but was far out paced by the general market indices. The contrast has been disappointing since as we all want biotech to do well.

M&A

On the Pharma M&A side, there were 25 transactions completed for a total deal value of $16.0 billion in the first three quarters of 2024 versus 29 deals worth $95.8 billion in 2023. Although the number of deals is repectable, the dollar volume has plunged. The pipeline of deals also continues to be modest with regard to pharma deals. There were only 9 deals worth $2 billion annouced but not closed at the end of the third quarter.

The are a number of reason for this significant drop. Big pharma has shifted their focus over the years. They recognize that while there were benefits from pharma mega-mergers, they did not accelerate innovation. As a result, pharma has focused on acquiring small to medium size biotech companies. They are also increasing strategic alliances, joint ventures and licensing. Pharma M&A is not driving their strategic focus.

With regard to Biotech M&A, there were 56 deals worth $72.9 billion completed in the first three quarters of 2024, which was significantly higher on both a annualized dollar volume and number of deals basis compared to all of 2023. One of the deals was a rather large deal, the acquisition of Karuna Therapeutics by Bristol-Myers Squibb, but that deal does not dominate the total number or dollar volume. Part of the reason for the high Biotech M&A volume is because biotech companies are having trouble going public and are being forced to sell early. When IPOs were plentiful and at high valuations, biotech companies could wait to sell their companies. Another reason for the increase is Big Pharma's strategic desire to acquire in specific therapeutic areas. As such, we are at record levels of biotech M&A. The buyers are also primarily U.S. companies.

Financing

On the debt side for Pharma, Big Pharma generally has a lot of cash and generally only borrows when they are trying to adjust their balance sheets after M&A transactions. The volume of debt issuance has increased in first three quarters, driven by lower interest rates and biotech M&A acquisitions. Equity offering volume has been higher as well in the first three quarters of 2024.

In Biotech, debt issuance is generally modest due to their lack of positive cash flows. However, the story regarding equity issuances is interesting. The total equity issuance market rorared back from last year, but most have been secondary offerings, not IPOs. IPO volume has recovered from trough level with 19 in the first 9 months of 2024

compared to 13 in all of 2023. The equity offering totals are not as high as they were in 2019 and 2020, but they are still healthy.

Outlook

The business outlook for pharmaceutical companies is positive. It has been a good time for innovation and Pharma companies have been able to fill up their pipelines with promising products. Overall development activity has been strong and will continue to be strong, with new technologies being developed. There has also been a shift to weight reduction, gene therapy, CAR-T, immune system solutions, CRISPR, etc. The pandemic also boosted the industry's reputation. The only group that is challenged are the Generics who continue to face fierce competition from India and China.

The stock market will continue to be kind to Big Pharma, but biotech companies will likely continue to be punished with some small signs of a recovery. On the M&A side, pharma companies will limit their acquisition of other pharma companies and will focus on biotech company acquisitions, partnerships, licensing, etc.

Biotech companies are continuing to do well in terms of inventing new drugs and treatments, but their challenge today is the financing market. During periods of easier financing, many started up. Many are struggling as we continue to face the trough in funding. However, public biotech companies may continue to raise funds, albeit at lower valuations. The IPOs will continue to be depressed and biotech companies will struggle to get funding at attractive valuations. Partnering, licensing, an M&A transactions will continue to play an important role in specific favored therapeutic areas.

Biotech M&A will be robust because they are a strong source of new innovation, but there will be favored themes and therapeutic areas, so not all companies will find buyers.

**The Pharmaceutical Market: Trends, Issues and Outlook**

**DOUGLAS M. LONG**
**VICE PRESIDENT, INDUSTRY RELATIONS**
**IQVIA HOLDINGS INC.**

There is certainly a lot going on. The last couple of weeks you had multiple of weather events, a hurricane that ravaged North Carolina and put down 70% of the saline supplied in the United States and a tornado that hit Wilson, NC and the sterile injectables plant. You had arrests made in opiods cases which raises a question about drug monitoring. You had the CEO of CVS step down, Walgreens announcing that they're closing 1,200 stores and Rite Aid going into bankruptcy.

Some of the industry challenges include the Inflation Reduction Act (IRA). Second, the Drug Supply Security Act that has been 10 years in the making but still delayed until next year. We'll talk about abandonment, the work people have to do to get people to take take their prescribed drugs is a challenge, with only 31% of the people that actually started on a prescription taking it at the end of the year. With regard to Biosimilars – I am concerned about the fragility of biosimilars and the three players went into different markets, yet there are a lot of untapped opportunities. The IRA changes and reimbursement challenges have been causing retail pharmacies a lot of stress; for example they lose money in every GLP-1 prescription they dispense. The DIR fees (direct and indirect renumeration) went to prospective instead of retrospective. And then you had the cyber attack that affected the system for about 3 weeks. Staffing issues in hospitals, pharmacies, nurse practioners and others just add to the overall problems.

Now I want to take you through a few charts from our Institute of Medicines report and our healthcare utilization index. We first did this in 2020 before COVID and this chart shows 2022 through the end of 2023. You can see the only item that is indexed higher was new prescriptions, but visits, screenings, elective procedures and vaccinations are lower. Many stepped up to get the RSV vaccine when they came out, but cases of polio have also started to appear around the country.

There are 6 trends that we pulled out of the report. First is the increase in drug shortages, particularly with regard to generics and injectables. This is not being resolved. It may also be a bigger problem going forward with drug inspections being down. Although the opiod epidemic overall is going down and we are back to the levels equivalent to 2011, overdose deaths are going up primarily to fentanyl and methaphetamines. Another interesting thing is contracteptive use is down 3%. Another trend is the growing use of immunology treatments, with immunology treatments for Crohn's disease, plaque psoriasis and many other indications. Even though Humira has lost its patent and is now facing more competition, the whole franchise is growing. The next are the GLP-1 drugs which is probably the biggest thing that I have seen in my life. There are also increases in drug volume in a variety ofmarkets, including antibiotics.

Over half of new prescription medicines are now going unfilled. Here are two different versions, one is on acute and chronic new active substances. Let's say there's 100 prescriptions. 51 of those are rejected, 17 get approved by a new payer so that's 65 of the 100. 18% is abandoned so new drug prescriptions is 46%. Then on products taken with persistency, you see 100% single fill and only about 31% are on it at the end of the year.

On current market performance, the market is at an invoice price basis of $757 billion. Specialties count for 51% and biologics are counted in specialties. GLP-1s are classified as traditional medicines. Interestingly, when COVID hit, the COVID medicines were considered traditional medicines. So specialty medicines are growing at 12.5% and traditional medicines are growing at 10.8%. A lot of the traditional medicine growth is driven by GLP-1. Retail, non-retail and mail sales are all up double digit percentages. When you break out the non-retail, where most of the action took place during COVID, we see that in 2020 long-term care and hospitals went down. With clinics still running, it has been a bumpy road, but drugs such as Veklury for COVID got as high as $4 billion in sales.

This next chart shows the compound annual growth rates. If you are above the line, you have momentum. Above the line are vaccines and obesity drugs. Below the line you see HIV, oncology, immunology, and diabetes. In HIV, there are a lot of generics. In oncology and immunology there are many biosimilars. With the Inflation Reduction Act, insulin is now $35 and that has taken $10 billion out of that marketplace. You would think that if the price of something goes down, the utilization would go up but that has not happened in the case of the impact of a $35 insulin.

So immunology, antidiabetes, oncology, antithrombotics, respiratory, HIV, vaccines, mental health, multiple sclerosis and diabetes are the top 10 therapy areas. Anti-obesity excluding diabetes is now a $13.5 billion category. There is softening in immunology and oncology because of biosimilars. Next are the largest retail sales, no surprise that Ozempic is the largest. In terms of largest absolute growth, we see Ozempic and Mounjaro at the top. Some of these drugs are facing patent expirations or the IRA. For the ones that lost the most, generally they have needed to switch to another product or they have lost their patent. For the top retail products, ACE inhibitors are down but calcium antagonists are up, so it is a mixed bag. When you are entering a market, you will see that 80% or more of the retail business is traditional medicines and a majority of mail retail business is specialty, as well as the majority of non-retail.

26 new product launches were made through June 2024. You can see 15% of the launches were in immunology, 15% in anti-infectives and 15% in digestives. As we look at 2023 and 2022, the biggest share of products was oncology, with oncology being the biggest innovation products. Mounjaro was the top product in 2022, Zepbound in 2023 and nothing of that magnitude in 2024. The launch trajectory is again not as high as before. In terms of the biggest launches in 2024, we see Octagam from Pfizer at the top, with a lot of these for specialty drugs. But first year launch revenues are down. Other than for Hepatitis C and COVID drug launches, we can see that the average first year gross revenue per brand for launches is down.

Generics, like Peter was saying, is in a race to the bottom. Things are starting to improve but that's only 5% growth in markets that are growing by double that. So you have 89.4% of all prescriptions dispensed in the United States being unbranded generics but that unbranded generic number only translated into 7.3% of the dollars and the dollar contribution is dropping by each year. Why is that? I think the biggest reason is 3 buyers control 91% of the market. The FDA is approving record numbers of ANDAs and there are a lot more players coming from India into the marketplace that has changed the dynamics. We can see that biggest depression in pricing was in 2022 and you can see the bumpiness in 2024 due to a changed methodology. Prices of the top 20 molecules have further depressed by 20% since 2019 to a point that it is hard to be profitable in the generics space. That is a recipe for drug shortages.

The next thing, is that 2 products, Ozempic and Humira are now bigger than the whole generic industry. That's 2 brand molecules that are bigger than almost 1,100 generic molecules. It used to be 3 in 2021 and 7 in 2018. Next is the number of molecules that got approved but did not launch. It used to be 75% would launch, then 50% last year, and now this year it's 23% through the second quarter. Another trend is the plateauing of sales from biosimilars of drugs such as Humira (Adalimumab). On drug shortages, there has been some changes on the reporting of drug shortages. The largest inspection was of an Indian plant who was inspected and staff were actually burning records as the FDA walked into the facility. As a result, their closure tied up 50% of the generic cisplatin and generic carboplatin market. They also happened to be the lowest cost provider and caused difficulty particularly for the rural hospitals. These shortages have been persisting for more than two years. Akorn was also the largest provider of children's albuterol in hospital and recently went out of business. The shortage you hear about the most is ADHD drugs since there's a quota on ADHD drugs. The FDA is also facing challenges on inspecting plants and inspections are down since COVID, with roughly 2,000 facilities that have not been inspected since before COVID. If we think drug shortages are bad now, when they start to inspect some of these plants, what will happen?

You can predict what kind of flu season we will have by looking at Australia. They are 6 months ahead of us, and they had an average flu season.

Retail pharmacy stores have also declined with 58,752 in 2018 to 53,480 as of June 2024, which is about 6,000 fewer. This is also before Walgreens announced another 1,200 closures and CVS said they would close 300 per year.

Think about how much workload goes to the next pharmacy as these pharmacies are closing. If you add reimbursements of GLP-1s, DIR fees, cyber attacks and retail theft, retail pharmacies are being squeezed on the back end and on the front end. We can see that the workload has increased per pharmacy with more annual prescriptions for stores and with more 90 day scripts, to be viable they will have to embrace AI. Adherence is also difficult as we see many Medicaid prescriptions are free or very low cost, yet patients are not adhering.

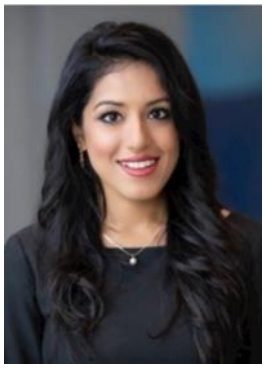
On GLP-1s, they have had an immense impact. 51% reduced their grocery spend after taking GLP-1s and their average grocery spend declined by 11%. What are they having less of snacks and confectionary, prepared baked goods, soda/sugary beverages, alcohol and processed foods. As such, the GLP-1 market has grown tremendously, $81 billion in 2024 and over $100 billion early next year. It is a retail-oriented class, some in mail and some in non-retail. There are some independents that do not want to fill this drug and it is often mostly 30 day scripts. There is an obesity gold rush where there are over 120 companies in development with the next product to get to market from Amgen, I think. It will be interesting as Ozempic is most likely going to be regulated by the IRA and generics will also enter the marketplace.

Opoid prescription deaths has continued to go down, but what has gone up are the number of fentanyl deaths which account for 70% of overdose deaths. Generally, people who have overdosed did not have a prescription for it in the first place.

On the outlook, we see obesity drugs and vaccines will continue to set themselves apart in terms of growth. There are still plenty of opportunities in oncology and immunology. We also see exclusivity losses in biologics forcasted to reduce revenues by $61 billion up until 2028. This is $33 billion of loss for small molecule drugs. In pharmacies, the role of pharmacies is changing as the closer we can get to patients, the better off we are such as immunizations and naloxone services. Elective procedures and screenings have not fully recovered from pre-COVID levels along with vaccines. Telehealth has become more specialized, mostly for GLP-1s and sexual issues. Launches are not as successful in today's landscape and generics are slower to enter the market. The biosimilars are also slowly making some headway, such as Adalimumab. We talked about the problem of abandonment, and generic deflation is slowing with specialty drugs continuing to grow.

The last thing is to look at the FTC and the battle against the 3 PBMs.

**The Impact of Artificial Intelligence on the Creation of Medicines**



**NAJAT KHAN**
**CHIEF R&D OFFICER, CHIEF COMMERCIAL OFFICER**
**RECURSION PHARMACEUTICALS**

**FRED HASSAN**
**DIRECTOR, WARBURG PINCUS**
**FORMER CEO OF SCHERING PLOUGH AND FORMER CEO OF PHARMACIA**

Hassan: We are talking a lot about innovation and this bioscience century. We are improving our knowledge about disease pathways – better targets and better tools in the toolkit to get to those targets. We are really adding on the power of technologies and it is turning out to be fantastic. I gather 8 Big Pharma CEOs together once a year, and I had a great conversation with them in January. To my surprise, there are always two or three that are skeptical, but with AI there was a remarkable consensus and they are all moving forward. They do not know exactly where the low hanging fruit is, but there are very excited about the whole prospect. Najat Khan, who I have known for many years, is a very well known person in the pharmaceutical industry. She has a science and tech background and is now the top person under the CEO at Recursion where she moved recently by taking a courageous step, moving from Johnson and Johnson, where she did a fantastic job.

Starting with the first question: recently the Google CEO said that AI is like electricity. Electricity arrived in 1880s and many industries grew as a result of it. People didn't know exactly where the applications were, but they continued to grow. He said that AI is like electricity in that there will be applications everywhere and it is only 5 years away from becoming mainstream. He also mentioned how ChatGPT gained 100 million users in a year, one of the fastest adoption of technology. What is your sense – is this like electricity?

Khan: Thank you Fred. First of all, an honor to share the stage with Fred, one of the legends. Let us unpack the question a little bit. When you look at the power of AI, it is not just in one area. Can you write a prompt and can you summarize something – that is the easy stuff. The next thing is can AI generate new ideas for you? That is the harder step where sometimes it hallucinates and sometimes it does not. It can also work at a pace that's quite astonishing. If you think about it in the healthcare space, can we do thing into a digital format and can we predict and design better molecules given that 90% fail to get a drug to market?

There are applications of AI across the entire spectrum, and that is why I think it is like electricity. If we take the pharmaceutical space as an example, the use of AI is across improving the probability of success and efficiency. In terms of looking at it from a probability of success standpoint, everything starts with understanding what is driving the disease. Today we look at it from a single target perspective, but the truth of the matter is often there are more than one protein at play, for example. Polypharmacology is the reality. How does AI play a role? You're using machine learning, large scale multi-omic data to understand not just a protein in a cell but the holistic aspect around the cell expression.

You know the problem but how can you make a molecule? Many people will quote this number in small molecular chemistry of 10 to the $60^{th}$ permeatations you can make. The true power of it is generative AI. There are molecules being developed that I would have never imagined. Generative power allows you to start from a much broader space. Once you get into the clinic, it becomes real. Are you targeting the right patients? Often we do not. You can also use multi-omic data to pinpoint the right patients. One example is RBM-39, a degrader in the oncology space, solid tumors akin to CDK12/13, which is very hard to draw. People have been trying to develop this for 4 or 5 decades. From the insight, in terms of the biology, to developing the molecule, and getting it to the start of the

program in the clinic – it took 18 months. Generally that takes 50 months in industry. The reason is that there is a completely different approach in how you identify the biology and the chemistry and how you get it into the clinic. So there is an efficiency benefit since you do it in scale, but I am more focused on the probability of technical, regulatory and commercial success.

Hassan: Peter said earlier that the biopharma industry is a great area for AI since it has so much complexity in it. Yet, the uptake appears to have been very fast in other sectors compared to biopharma. Is there a mindset challenge among scientists and the rest of the industry? I have heard that commercial uses can be a very good low hanging fruit area but a lot of the commercial people have mindset issues. Any comments on that problem in terms of adoption?

Khan: That's a great question. Having been the chief data science officer at a large biopharma company, I can tell you a lot is the mindset. Pharma industries in general have high margins so whenever a company or an industry has high margins, what is the reason to change? That is the truth of it. Do we have a burning platform? In the day-to-day, a lot of the times, it does not feel like there is a burning platform since it takes nine years to make a drug we will have X, Y or Z margins for. I hate to say this, but I think that is one of the reasons.

The second reason is just a lack of understanding of how to use this tool. Everybody knows what the pain points are but how do you deploy it? Sometimes it means your job changes. That is threatening. I have seen this first-hand and happen over generations - electricity, steam engines, etc. I think that there are two ways to respond. You evolve or you get evolved. So how do you educate yourself? You don't have to be a coder to understand AI. It is like another science or technical topic. It's more important to understand how to use it and what not to do or what to do. Given the complexity of the pharma industry, the regulations, and the limited understanding of biology today, there is a fear of being personally threatened and having to tinker around with something that is very hard to understand and be successful at. Pharma is one of the most high-risk industry but it is also one of the most conservative industries. I have seen folks say that if I use AI and it messes things up, I will be 5 years behind, so I would rather not try. I do not think that is an option anymore. With the current success rate it will not be sustainable.

On the final piece, I founded a consortium called Disrupt which brings together the top 13 Pharma companies, and their AI leaders. We did a benchmarking that was published and what was seen was the land of pirates. Good ideas get started, but it is really hard to scale because there has to be top down approval. CEOs will say we should do it, but the next liutenant in charge does not agree or says that they do not have the budget. Financial services has succeeded in specific instances and you start to see that in Pharma with the automation of documents, authoring it faster, etc. But this is not a game-changing advancement in how we make a drug.

Recursion is in the process of merging/acquiring Exscientia. One reason why we did that is because Recursion had its start in biology and Exscientia had its start in chemistry. You need both. At Exscientia, they have molecules such that instead of synthesizing thousands of molecules, they get to 200 molecules and to the right one. You are doing 80%-90% using the algorithm and then you get to the last piece which is the chemistry validation. This is a very different way of doing things. People in these types of organizations are "bilingual"- deeply knowledge in science, discovery, development, but also in data science and AI. The secret is to ensure that the excellence is equal in both disciplines and you pull it through in the decision-making.

Hassan: They say in commercial, the old marketers need to be bilingual in data first, omnichannel first. It is a different mindset and has the same challenges as you see in discovery and development.

The cost of healthcare, particularly in the U.S., is becoming unsustainable. We are getting close to the 20% mark. The industry is extremely innovative but there are massive barriers to innovation getting adopted and the industry needs to have a role in bending the overall healthcare cost. Can AI help deal with this problem of the total healthcare cost curve?

Khan: I will use an example from start to finish and we can tie it in with where it is happening and where it is not happening. One reason therapeutics costs a lot of money is because of our huge failure rate. We are going through

many assays and molecules that it takes 5-6 years. If you look at some of the companies innovating in AI, half the population are computer scientists and the other half are scientists, such as medicinal chemists. With a limited staff, the company has 20 programs in the pipeline and at first, I thought how? The reason is because you are doing so much computationally that you are failing using your computer, but not failing by going to the CRO, running an experiment and then running more iterations of that. You are also starting with a better hypothesis about what is driving the disease, so there is less searching. The way Recursion does it, you start with multi-omic patient data, not with mouse data that is then being translated to human. This is a lot of the failure rate that happens. 18 months compared to 3-4 years - that is a major savings. The next part is how do you run the trials. 70% of the dollars are for clinical development.. How do we find patients for trials today? We call clinic sites and ask for patients. We see when we run the analysis that this traditional method is not very accurate at all. Instead, we can use claims data and other real world data to figure out where the eligble patients are. Instead of 2 years to start up studies, you can do that in months. My example would be that I live in New York and Fred lives in Florida. If I wanted to see Fred, I would not go and ask everybody on my road trip "where does Fred live?" That is what we do today. I would instead use Google Maps to be really smart and go straight. By this analogy, we are putting the patient in the center because of the fact that we are using data. We can then reduce the length of the trial and use multi-omic data to predict which patients will respond or not. This reduces the amount of time needed in the clinic by being smarter. With commercial, you can use the same data used to recruit patients to figure out which principal investigators or which physicians to go to. Sales folks will say they do not need the data, but it augments them; it does not replace the salesman as long as they know how to use it. The amount of efficiencies to be gained over reauthorizations, documentation, and physicians writing reports is immense. These are low-hanging stuff. There are a number of inefficiencies that you can take out of the system but the grit and resiliency to keep working at it is essential.

Lastly, it may be controversial, but it is interesting what Lilly Direct and Pfizer have done in one area. They have a system similar to telehealth where you can meet with the prescribers and they can deliver your prescriptions to your house. There is a lot of conversation whether this is the right thing to do, but if you ask patients from an access perspective, they love it. If you look at the cost, it is a tenth of the cost that it usually takes to get a drug to the patient and see the patient. There is also a higher percentage of being reimbursed per their terms.

**The Changing Roles and Relationships- Biotech and Pharma**

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Young: I am pleased to have two people from different points of view to talk about the changing relationship between pharma and biotech. When biotech first came out, they didn't have salesforces or teams of people who were good at clinical trials. They were mainly good at inventing. Their relationship with Big Pharma was a reflection of the pieces they did not know how to do – the salesforce and the clinical trials. Over time, things have changed. Biotechs had more choices with regard to who they can use to do the clinical trials. With orphan drugs, if there are only 3 research centers, you don't need to partner with Big Pharma to have an effective sales force. In addition, for awhile biotech could raise money at high valuations and could put off when they sell, license, etc. Today, depending on the biotech company, their relationship with Big Pharma is really quite different from years ago.

I would like each panelist to first introduce themselves.

Zweifach: Great, thank you. Just on the AI comments made earlier, I am involved in a company that's involved in data. Bio data, drug development data and processing using machine learning. Everyone uses the word but I challenge everyone to give me two sentences that explain what it is. I do not even know - it is a black box. There has also been many failures in this space. Every day I spend a ton of money and things have not worked; that does not mean it will not work but it is the reason for the skepticism. I think why people are not implementing it is that they do not know what it really means and are scared of it. It is similar to the manufacturing business. Automation suddenly takes away jobs, which may lead to better cars, but causes a lot of worry in people. Especially in Big Pharma, you cannot bring them a program that may threaten their budget, no less a new technology such as AI.

I will now introduce myself. My name is Sandy Zweifach. I was a scientist turned businessman who got back into the business of science 32 years ago. I have seen it from the pharma side, the biotech side, the banking side and the VC side. I have tried to do deals with J&J and have been shut down by commercial. They run the roost and at the end of the day, you need to have a commercially viable product albeit great science. I sometimes bring them label expansion ideas with AI and they insist that their commercial team knows everthing well. That is what we are up against in the biotech industry. I am currently the president and chief business officer of a company based in Barcelona that develops autoimmune disease drugs and I sit on a bunch of boards in the industry.

Christel: Glad to be here today. My name is Michael Christel. I work for MJH Life Sciences on three brands – Pharmaceutical Executive, Applied Clinical Trials and other magazines. We are focused on leveraging AI to generate content, but also covering it. We get inundated with pictures and stories of AI, but what we are looking for now are some case studies of how AI has been applied successfully in the industry.

Young: The relationship between biotech and pharma is complicated. It does depend on which therapeutic areas and what technology that you are developing. Let us start with how would you characterize the relationship between Big Pharma and biotech today and then drill down into the differences.

Zweifach: I would say schizophrenic. Pharma is always changing. They change their therapeutic areas of focus, they change their budgets, etc. Six months ago you can bring something to J&J or Lily and they have no interest whatsoever. Six months later they will be shocked that you did not bring this to them before. If there is no interest today, that does not mean there will be no interest tomorrow. You need to have the capital to sustain yourself. You have to be a marathon player. You need to have conviction but also be reactive to what is happening in the market. CNS was a dead area years ago, but today CNS is a hot area. Autoimmune, similarly is a hot area. But how do you differentiate yourself? At the end of the day, you need pharma to lead your market future. Especially with the IPO market not being robust, that is your answer. When the IPO market was crazy, people did not talk to pharma. It is an ever-evolving relationship.

Young: So, you have to be very resilient and realize that Big Pharma keeps changing their opinions.

Zweifach: You have to first believe in your own science and have conviction. Obviously, you also need to attract capital. After that, you have to read the market. However, if, for example, you have a cardiovascular molecule that you think is going to be a winner, convince somebody and get the conviction.

Christel: I agree with everything said. Following the different dynamics, the relationship has changed over the years and is constantly changing. Especially with the IPO markets and evaluation markets skewing towards pharma over the last three years; Big Pharma has all this capital to make deals. Previously they were just sitting on this capital. What can biotechs do to differentiate? Is it going to different therapeutic areas? Is it latching on to the next gen therapies? Do biotechs need to change their business models, by tapping into these new trends? Can they draw upon the science of models from years ago?

Young: To combine what the two of you are saying, it is very important to have a thoughtful strategy and to pivot. You have to believe in your science and believe you are solving problems better. However, it does not always end up with a relationship with Big Pharma. Evan Loh, the CEO of Paratek, figured out long before that Big Pharma was not a pathway. They developed a series of new antibiotics, where the problem is that they can actually cure you. It is not like statins, where you are on the prescription forever. The other is that these bacteria develop resistance which makes raising money for this company difficult. Depending on what area you are in, your end game may not be tying up with Big Pharma.

Zweifach: Another mistake of biotechs is that they look at a handful of companies, per say the “Lebron James” of biotechs. They see them raise a lot of money and think that they are good. Mark McKenna raised $400 million for his latest company because he made $11 billion from his recent investors. I asked a bunch of the guys I am friends with, why do you put money in there? They say: I gave him some crumbs; I made $4 billion off of him, give him $100 million, it is nothing to me.

I think a big mistake of biotech in general is not being self-aware of what your value, the total package, is to the marketplace. Your science, your people and your opportunity set. I will say that AI can help biotechs run more efficiently. We see biotechs get overloaded very quickly and then they have to quickly downsize.

Christel: There are some examples that we have explored where biotechs are not only looking at Big Pharma. One example was when I did an interview profile with Genmab, and they have had an interaction model over the years. They have understood the model over the years. They have partnered and sold off their royalties for over 25 years and their business model has always been royalty driven. Lately they have transferred their business model, and they are now acquiring smaller tech-driven focused biotechs. They recently acquired ProfoundBio, an ADC specialist. They were thinking we want to add these assets from targeted areas that are hot right now. They have licensed to Big Pharma previously but are now putting eggs into the commercial basket. We are seeing that transformation in biotech.

Young: I like what you said, Sandy, about being creative about how you design your spend rate. We are doing a financing for one company and the competing company hired people too early, but then had a delay at the FDA and is just burning cash. Another extreme example is a story on a company called Allopex Therapeutics from Boston. They were funded by the Pritzker family and I was friends with the family who told me to please go see the CEO. I go to the address and knock on the door, realizing it is his house. He told me to come into my office and we went into his kitchen. He was the CEO, they outsourced everything, and as soon as they could, they developed a partnership with Sanofi. They designed their partnership such that after the clinical trials, there was a tremendous incentive for Sanofi to buy them out. He never hired employees and the research was done out of a university. At the end, Sanofi bought them out and he never needed to raise additional money from the seed round. Now that is an extreme example, but it is a great example of thinking outside the box. Do not think conventionally and do not think of the M&A and IPO markets or Big Pharma in the conventional way.

Zweifach: It is a very confusing relationship and there is no formal, set way to do it.

Young: For the two of you, are there any technological or structural changes in the industry that will change the relationship between pharma and biotech?

Christel: You can see in the financial markets that many biotech stocks are doing better now. We can see from KOLs that many biotechs are relying on their fundamentals. On the flip side, you get the sense that many biotechs are looking at the commercial end of it as well and building it into part of their strategy. Normally this is not on their minds. You are starting to see what the playbook for biotech should be. I think there is more focus on that and more focus on how they can engage the communities, bring in expertise, and tap into the partners. You want to see a great asset but also using AI to map the commercial landscape as you move the program forward. I am seeing more collaboration.

Zweifach: Because of AI, everyone knows what is out there. If you are a biotech and not using AI, you likely have a blind spot. You can have a literature search blind spot. If you are not using that tool at a minimum and you go to Big Pharma who has opposing literature, you are done. I do think they are a lot of beneficial uses that are promising.

**Speakers Roundtable- What Does the Future Hold?**

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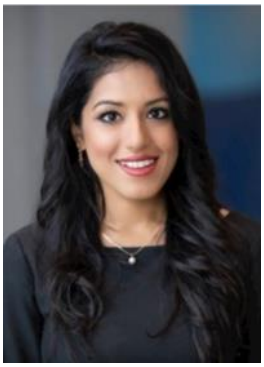

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Young: So the first question must be the obvious: with the elections coming up, there are a lot of things happening. What areas are likely to have some change after the elections and what do you think the upcoming elections will impact the industry?

Hassan: I will start. Regardless of our opinions on individuals, I think President Trump knows business and can be good for the U.S. The amount of savings on the side of IRA are very little, $7 billion last year and is destroying the confidence of spending money on R&D. No politicians however can answer the question of how come small molecules take nine years, big molecules get 13 years and small molecules are cheaper for society than big molecules.

Christel: The IRA is huge and we take an objective view on it. For companies it is the cost savings to the patients, which has been little, but our interest is how biotechs strategize around it. It is a big focus of market access. It will be an uncertain kind of reimbursement.

Zweifach: I have not seen any change in VC wanting to invest more in small molecules. I have not seen that decrease the attraction to small molecules.

Khan: From a biotech or pharma perspective, folks are thinking about indications and indication sequencing. I would consider there are many backup strategies but the impact has been more muted. In biotechs I see a huge

concern in rare diseases and whether people want to go for multiple indications. It is just so hard to make a drug. Do you want to put more guardrails? Why does it cost more to develop the same drug in the US v.s. ex-US? It is easy to have a single throat to choke but we need to look at the problem holistically.

Hassan: This is a pattern around the world. Healthcare budgets are under stress. When governments have to make choices, they go after the drug companies because there are local politics involved with the hospitals and doctors. This is the best opportunity to innovate in the next several decades to bring down the cost of healthcare.

Marks: I do not disagree and what I have seen from the FDA and from the industry is that there are aspects of the IRA that are anti-innovation. I have my suspicion that whoever has control of congress, there must be something in this area. Both sides understand that there are some very perverse incentives here and biopharma is a national strength.

Young: The FDA does a terrific job at evaluating drugs and ensuring safety. However structurally, the U.S. consumer is subsidizing overseas patients and the FDA does such a great job that many piggyback off the FDA. The FDA is doing a lot for the countries as well.

Marks: We do not mind. If we can help our ecosystem by providing good reviews, we can get these products onto the market more rapidly. It is good for business to have a robust attitude. I do not see this as a negative.

Young: On the next question, there is a rising question of competition between the West and Asia, particularly China. China is making rapid progress in development of drugs and biotech is one of the five industries they declared in their 2025 plan. India is also serious competition. What are your comments on where things are going to head in the next 5-10 to 20 years?

Hassan: I met a lot of entrepreneurs and it is truly remarkable how this has changed. Last year, half of the INDs for pre-phase I were from Chinese origin. They have a five year plan to be a strong challenger to the U.S. It seems to have come along nicely since they have tremendous brain power and returning multinational talent. They are especially strong in cancer, ADCs and CAR-Ts. India is also catching up very fast but not like China.

Marks: I agree and for me it is especially hard on the manufacturing side. Sustainable manufacturing is a challenge on the pharma side. China has amazing to watch, especially in their CAR-T development. There is some more opportunity to directly adminstered genes in the U.S. It really depemnds on where we put the investment and whether it is hospitable to move these things forward rapidly.

Khan: I couldn't agree more. In the last six months, China, for example, has gained a little bit of aggression. There are so many great companies and great molecules but due to policies and politics, there is a regression. I have many entrepreneurs that are having to license things that they would not have before. South Korea is also picking up. On India, it goes back and forth, but it seems they are having a tailwind of U.S. companies thinking of APIs and contracting CRO shipping with India APIs. There are also policies that challenge being associated with certain companies in China. There is a strategic shift there. There are also more people coming back from the U.S. or who are trained in the U.S. going back to China.

Zweifach: I spent five years running a company in China where after FDA approval, we were then financing Big Pharma's drugs in the Chinese market. In the time I spent there in China, I know China is a long-term player in everything. You name the area, they are in it for the global, long-term play. To think they will not be dominant is

naïve. We would not have our phones today without China. We will have drugs that we will use that will come from China.

Young: With India, they have always been on the verge of moving from APIs and generics to more advanced drugs. China will be serious competition for the West unless the West has a thoughtful industrial policy in biotech. The only way China does not ultimately succeed is because other parts of their economy implodes. The other thing is that students from China used to stay in the U.S. The government has prosecuted 250 Chinese scientists across all fields and there are only one or two cases where the spying was true. One case there was a Chinese scientist who was wrongly accused because she worked late. Anti-China also happens to be the only bipartisan issue. It is right to worry about China, but some of the things with the China Initiative that they have done has made it worse for Chinese students.

Zweifach: The Chinese government does not have to ask it, they tell them to do it. They are in a closed system.

Young: Often our industrial policy is structured improperly. We do not always have thoughtful government policies to advance industries such as the drug industry. An example worth mentioning is in semiconductors. They are trying to build semiconductors in upstate New York but there is not the skilled labor for it.

Young: The last question is what are the new challenges that biotech and pharma will face that we are not thinking about today.

Hassan: I think it is the workforce of the future. We are at a state where we must be bilingual with the computer science, as Najat said. I think we will need to be trilingual and understand marketing and sales. Working cross-functionally will be very important although pharma has traditionally been silo based. The challenge is will we be able to work in a silo free environment.

Khan: I was talking to somebody about being trilingual and whatever your domain is, it is important to good leadership skills. You have to have a high bar when choosing a probability of scientific and commercial success. Often in R&D we promote based on how good you are as a scientist, not a leader. I have had people tell me to slow down, and let the 5-6 years to get into a clinic and then another 5-6 to get a drug approved happen. I think the ecosystem is evolving very quickly and I think knowing how to work smarter will be very important.

Marks: One of the things I see is that as we make more complex biologic therapies, is that the delivery of these products will be more complicated. The patient experience is very intertwined with the delivery. People will have to think about how to develop your therapy such that the delivery end is smooth as well.

Zweifach: Phones may become obsolete, but our industry will never be obsolete. Unfortunately, we will never solve or cure all diseases.

Young: I am optomistic about the long-term success of pharma because there is a big need. There are examples in real-life example where technological changes dramatically changed the global or geopolitiical dynamics. Ukraine and Russia are showing that drones are king and the standard of warfare technology may have significantly changed. Cyber warfare is another example of how changes can dramatically change the relative power globally. Many of the military heads are in a panic, especially the U.S. where our military power is based on $30 million jets and very expensive ships.