



IAMERS Newsletter

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January 12, 2009

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Letter from the President

Dear Members,

2009 is off to a busy start for IAMERS. Our first project of the year will be Arab Health. As you may know, this is a first for IAMERS. IAMERS will share booth space with six of its members. As well, we will have a member's (and their guests) reception on Tuesday night, September 27th. Hopefully, everyone who plans to join us for the IAMERS reception has already RSVP'd. We want everyone to have plenty to eat, so we always ask that you RSVP to IAMERS events.

Our second event will be the ECR in Vienna in March. IAMERS will have a member reception, as we have the last two years, on Sunday, March 8th. Details on all our member events, including the Annual Meeting in San Juan, PR, are noted on Page 7.

At the same time there's a lot going on with the FDA. I'm sure many of you have heard that further regulation is distinctly possible in the near future. One of the specific areas receiving attention is the suggestion that FDA has been too quick in their approval of devices. Certainly, I am nervous about what I read. Please note that IAMERS continues to stay on top of this subject. We will continue to work to protect the interests of our members. We welcome any ideas or comments you have regarding this subject. The more people contribute to this issue, the better able we'll be to direct our activities.

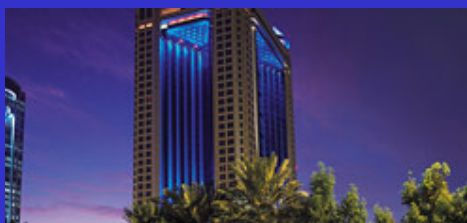
As you can see on Page 7, IAMERS will also spend time at various trade shows throughout the year. The shows where we only have a booth are to increase awareness of IAMERS.

Send us your suggestions. We always appreciate comments that we get from members.

I look forward to seeing many of you during Arab Health.

Cheers,

Diana



Arab Health • Jan 26th – 29th 2009

IAMERS Members Reception ♦
Fairmont Hotel
Tuesday 27 January • 7 – 9:30 PM

♦ RSVP by January 20th

IAMERS Welcomes New Member

X-RAY CONNECTION

Carlos Lopez

1790 Ellis Street, #9

Concord, CA 94520

Phone: 510-315-2211

Email: xrayconnection@yahoo.com

Website: www.medmatrix.com/xrayconn

Sells pre-owned diagnostic imaging equipment

Burj Al Arab

The Burj Al Arab – “Arabian tower” was completed in 1999. It’s the only 7-star hotel in the world; and also the tallest hotel in the world. Built on its own artificial island against the backdrop of the Gulf; it has become the international symbol of Dubai.

It has a helipad on the 28th floor, a restaurant seemingly suspended in mid-air, an underwater restaurant that you get to in a submarine; and much more.

The billowing sail of the traditional Arabian *dhow* was the inspiration for this contemporary architectural masterpiece.

Access to and from the hotel is either by the causeway – via one of the hotel’s Rolls Royces, or by helicopter.

The sail portion of the Burj is covered by a stretched translucent fabric, a Teflon-coated woven glass fiber. No other building in the world uses such technology.

Only suites. Sorry, but no standard doubles are available at the Burj Al Arab.



IAMERS @ Arab Health

In just two weeks IAMERS, and six of its members, will share a booth at the 2009 Arab Health Congress in Dubai. The six companies are:

Agito Medical
Bay Shore Medical
Diagnostix Plus
Lundy Healthcare
Metropolis International
RSTI

If you are attending Arab Health, please come and visit us:

Booth # 1C39
in the American Pavilion

IAMERS will also hold a reception for members and their guests on Tuesday night at the Fairmont Hotel. The Fairmont is across the street from the convention center.

Fairmont Hotel
Sheikh Zayed Road
33rd Floor

Tuesday, January 27th
7 – 10 PM

All those who plan to attend, must be pre-registered. If you are not pre-registered, please do so. Registration is closed after January 20th.

Please note members cannot bring ex-members as guests.

This is the first time that IAMERS has shared a booth with members. It’s also the first time IAMERS has exhibited at Arab Health. We hope to learn from the experience. Whether you are one of the companies sharing the booth, or just an observer, please let us know what you think. This was a time-consuming endeavor on IAMERS’ part. We want to know if it was worth it – for you and for the Association.



Change of pace from a marble-floored mall? In Dubai, try a souk. A souk is an Arabic Market. Traditionally, dhows from China, India, and the Far East would discharge their cargoes; and the haggling would begin in the souks adjacent to the docks. Pictured herein are the gold (above) and spice souks of Dubai.

The Nine Lives of CAT Scanning

Wayne Webster

If there's one imaging technology that consistently lands on all fours it's CAT (CT) scanning. Introduced in the 1970's CT scanning quickly became the gold standard for radiology. With the passage of time computers improved, displays became more functional and protocols were developed to image every part of the body. Radiologists grew to count on CT for accurate anatomical imaging.

Several years ago CT was considered standard technology. You had to have one if you were going to operate an imaging center. But, as we moved into this century CT was reborn with multi-slices, large detectors and new applications.

Recently three articles were showcased in *Imaging Technology News*. They caught my eye because each speaks about the "New" CT. They say a lot about where CT is today and point to where it's going for good or bad.

The first article was from a December publication of the Journal of the American College of Radiology. They published a study showing that non radiology physicians are acquiring CT's at a higher rate than radiologists. The study covered the years 2001 – 2006. You'd think in a time of concern over self-referral that this would not be the trend. According to the article, whether it's the number of scans or scanners ordered non radiologist are out pacing radiologists.

These aren't all going to cardiologists either. The study found that non radiologic specialties with the largest volume of scans in 2006 were primary care physicians. Excluding independent diagnostic testing facilities (IDTF) the non radiologists' private office CT market share rose from 16% in 2001 to 28% in 2006.

One would assume that the areas scanned related to the specialist's area of expertise. The data suggests that this is not always the case. In 2006 more than 99% of the urologists' scans were of the body. The same was true of medical oncologists' scans. 74% of vascular surgeons' scans were cardiovascular. 72% of cardiologists scans were cardiovascular and 67% of neurologists' scans were of the head or spine.

It's accepted that self referral leads to higher utilization and increased healthcare costs. I suspect those involved in the setting of reimbursement policy will be watching this area carefully as more non radiology specialists enter the market with their own CT scanner.

Imaging Technology News also reported on an article scheduled to appear in this month's (January) issue of the Journal of the American College of Radiology. In this study the authors expressed concern over the extracolonic findings that are an outgrowth of virtual colonoscopy. You may recall that virtual colonoscopy was recently endorsed by the American Cancer Society as a valid screening test for colon cancer.

In the January article virtual colonoscopy is termed computed tomographic colonography (CTC). I guess the word "virtual" made it sound like it wasn't real. Lincoln L. Berland who authored the article expressed a concern for the reporting and subsequent management of extracolonic findings which are a result of CTC.

The question is one of expertise. Are those making the diagnostic calls outside of the colon sufficiently trained to have a high degree of accuracy? If something is identified what is the cost if the diagnosis is incorrect? According to the article, some studies have suggested the evaluation of extracolonic findings is insignificant, adding only slightly to cost. Others who've more closely tracked cost say the increase can be five times higher than if the diagnosis was obtained by the appropriate specialty.

You may recall a few years ago imaging centers were adding whole body CT and advertising its ability to diagnose silent disease lurking within you. This was frowned upon by the medical community and it appears that the extracolonic findings although not the same sort of carnival like atmosphere will have a similar result. The extra testing and therapy for the asymptomatic patient diagnosed by someone diagnosing extracolonic events is not without cost and concern.

The third review was about the increased dose from CT and the efforts to reduce patient radiation exposure. Sapheneia, a global imaging services company is marketing a software solution for lowering the radiation exposure to patients from CT imaging. They claim that depending upon the anatomy being studied that the dose can be lowered by 20-80%.

Basically, Sapheneia software is said to enhance the image thus allowing the radiologist to reduce the power of the CT during the scan resulting in the same quality image as if the scan had been conducted at higher power and patient dose

Managing radiation exposure rates and maintaining quality standards for imaging is an issue for the CT scanning community. Fixing the problem in software appears on the surface to be a less costly approach. Adding hardware and redesigning the CT to get the same result most certainly will add cost to the healthcare system.

The Sapheneia press release offered little in the way of proof other than the vendor's claim of reasonableness and utility. I suspect there will be more software solutions from other vendors and these hopefully will be adaptable to existing hardware.

As CT continues to use its cat like nine lives as it's reinvented, sellers of pre-owned CT may find an opportunity to sell more equipment. As software and new applications increase the usefulness of current generation CT scanners, physician demand will grow.

Even in a time of economic downturn I predict that the sellers of less costly pre-owned imaging equipment are more likely be able to make the acquisition of CT imaging fit within available budgets.



Proposed Changes at FDA

Joshua Sharfstein, a former health care aide to incoming House Energy and Commerce Chairman Henry Waxman (D-Calif.), is considered a leading contender to become the next commissioner of the Food and Drug Administration, various sources on and off the Hill have told CongressNow.

While the pick is not yet a done deal, sources said Sharfstein's selection is potentially interesting for two reasons. One is that Waxman will be chairing the House panel that undertakes the task of crafting virtually all health care legislation next year. And the other is that Waxman has a reputation as an aggressive overseer of the federal bureaucracy, and putting a protégé in charge of a major agency that has had its share of critics could produce momentum for changes. Sharfstein, one of a handful of names floated for the position, declined to comment.

Among the other names in the mix are Steve Nissen, chairman of the Cleveland Clinic's Department of Cardiovascular Medicine; Janet Woodcock, a current senior FDA official; Susan Wood, a former FDA official who resigned in protest over the agency's delay in approving a contraceptive drug; Robert Califf, vice chancellor for clinical research and professor of medicine in the Division of Cardiology at Duke University; Dora Hughes, a senior Obama health care advisor; Mary Pendergast, former deputy commissioner and senior advisor to the FDA commissioner during the Clinton administration; and Ann Witt, a Waxman health care advisor and former head of FDA's Division of Drug Marketing, Advertising and Communications.

Sharfstein, the Baltimore Commissioner of Health and a member of President-elect Barack Obama's presidential transition team, previously served as health policy advisor on the Democratic staff of the House Oversight and Government Reform Committee, under the chairmanship of Waxman.

In that capacity, he was responsible for oversight and legislative projects on scientific integrity, HIV/AIDS, FDA oversight, tobacco control, public health preparedness and other health topics. He currently is advising the transition team on how the FDA can be improved and overhauled.

Sources on and off Capitol Hill said that Sharfstein is considered the kind of candidate who would send a message of change to an agency that, according to its critics, is too close to the industry it regulates.

He "sends a message that there's a new cop on the beat," an FDA consultant said. Sharfstein has an "impressive record in public health administration, policymaking and academics," Bret Koplw, an FDA lawyer with Patton Boggs, said. "His name is at the top of the list," a former FDA official added.

Given Waxman's central role in FDA reform next year, Sharfstein's relationship with the chairman would be a tremendous advantage, various sources argued. It is "better to have someone at FDA where Waxman has his back, rather than stabbing him in the back," an industry lobbyist said.

Sharfstein's relationship with Waxman, Koplw added, "could go a long way toward tamping down the 'cat and mouse' play that has characterized the FDA's relations with one of its most effective congressional critics."

Some sources questioned whether Sharfstein has enough administrative experience to take the job. But the other two leading candidates, Nissen and Woodcock — who also declined to comment for this story — are considered more controversial.

While consumer and patient groups respect and support Nissen, a frequent FDA critic, industry officials say he is too divisive and has engendered friction over the years with senior agency staff. The reverse is true for Woodcock. Industry tends to support Woodcock, a known quantity from her years as a senior FDA official, but she would be expected to face opposition from those who want to make a clean break from the current administration.

Woodcock is currently FDA's deputy commissioner and chief medical officer and head of the Center for Drug Evaluation and Research, and as such, she's been part of an administration that had made the FDA a "transmission belt for industry to get their products on the market," charged a government whistle-blower advocate.

Rep. Bart Stupak (D-Mich.), chairman of Energy and Commerce's Subcommittee on Oversight and Investigations, recently wrote a letter to the incoming administration, urging transition officials to look outside the current administration for FDA leadership.

"There are few places in the federal government where the need for change is more apparent than at the FDA," Stupak wrote in a Dec. 3 letter. "The American people and the thousands of hardworking employees at the FDA deserve a leadership team that will bring to the agency a renewed commitment to food and drug safety."

Stupak went on to allege that the current FDA leadership "blocked clinical trials, drove dedicated medical professionals out of the agency and lined their pockets with outrageous bonuses. The agency has abandoned its core mission of protecting Americans from contaminated food, unsafe drugs, and medical devices."

Whoever the next commissioner is, they will have their hands full as Congress considers a number of bills to overhaul the agency.

These bills include legislation to strengthen FDA's inspection of imported food and drugs, improve its own drug approval process and bills to give FDA the authority to regulate tobacco products and approve generic versions of biologic product. Key lawmakers, such as Waxman; Stupak; Energy and Commerce Chairman Emeritus John Dingell (D-Mich.) and Senate Health, Education, Labor and Pensions Chairman Edward Kennedy (D-Mass.) have taken the lead on these efforts.

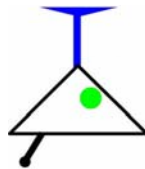
This call for reform comes as the FDA has been under fire from lawmakers in both parties who argue that the FDA is falling short in its efforts to protect Americans from tainted food and drugs as well as faulty medical devices.

The Democrats' main bill this year was the Food and Drug Administration Globalization Act. The legislation, which takes on the safety of imported food, drugs, medical devices and cosmetics, was sponsored by Dingell, Stupak and Rep. Frank Pallone (D-N.J.), who heads the Energy and Commerce Subcommittee on Health.

In addition, Kennedy and Sen. Chuck Grassley (R-Iowa), HELP's ranking member, introduced the Drug and Device Accountability Act (S. 3409) this past year. It would enhance registration of drug and device facilities and increase resources for inspections through collection of user fees.

Furthermore, Waxman and other lawmakers are trying to pass the Family Smoking Prevention and Tobacco Control Act (H.R. 1108), which would give the FDA authority to regulate tobacco products. He is also eyeing legislation to stop the direct marketing of pharmaceuticals to the public and to establish a pathway for the Food and Drug Administration to approve generic versions of biologics as well as to increase funding for the FDA and other health care agencies.

The Senate Health, Education, Labor and Pensions Committee has jurisdiction over the confirmation of the FDA commissioner.



Wayne's Thoughts on FDA Changes

After reading this I have thoughts of Social Security reform. Thank God we didn't reform it in light of the stock market meltdown. As Greenspan was heard to say when asked about the reasonableness of his belief in deregulation of our financial markets and self policing, I believe he quoted Emily Latella, a character created by Gilda Radner and frequently seen on the SNL News Update in the 1970's, when he said "Never mind."

But in the words of a great American scholar, "But I digress". No question the FDA needs updating and direction on a regular basis. Don't we all? But this intensity from Congress may prove to be a real issue. I suspect the continuing criticism of the agency will only make the changes more difficult to make. The Washington bureaucrats I've met in

this and other agencies under similar pressure seem to have an interesting attitude. I've often heard the battle cry, "We were here before them and we will be here after they leave."

There was much that happened in 2008 that should give rise to concern within the agency. Not so much for their lack of response but the process by which they anticipate problems that have yet to happen needs to be considered. Within the FDA there is a process called MAUDE. This requires that registered medical device companies read the complaints from users of medical equipment and view the solutions. Taking this information they are to consider if these problems could happen to their equipment and show FDA that they have considered all of these unrelated incidents and discussed possible corrections for their own equipment. What's good for the goose...Maybe it's time for the FDA to take some of their own medicine?

I believe we'd all do a lot better with someone in the FDA top dog position who is a successful leader and a manager of process. Although it would never happen, I'd put someone in there who is neither friend nor foe. A new face with no FDA or Congressional history would work well. There are plenty of expert worker bees at the FDA already to carry out the job through channels. We need a visionary and a leader.

It looks as if IAMERS members could be swept up in any reform that brings medical devices to the front. I was especially discouraged to see that Rep. Stupak put medical devices in that category with contaminated food and unsafe drugs as being unsafe and abandoned by FDA. That's scary. Maybe he should be on your list for a visit?

I've known the agency since the early days and have watched it as it slowed the process down so as to improve safety, the next administration demanded change and wanted things speeded up inevitably leading to the claims of callous behavior and the release of drugs and devices that somehow harmed Americans. My Dad, a career Navy man often said; "Sometimes you can't win for trying". I was never quite sure what he meant, but I think it related to the never ending changing of orders from the top as commands changed and they continued to sail in circles.

I suspect all of this bluster will bring change but not effective change. We as a nation are demanding change and I'm afraid we're going to get it!



We welcome into the world
Gabriel Lev Gugel
First born of Leon & Diana Gugel

Look how peaceful he looks.
Rest easy, Gabriel,
the world won't always be this easy.

*Don't forget your Sweetheart on
Valentines Day*



*Be Generous.
Best gift ideas:*

*Roses
Diamonds
Rubies
Cars*

Running for Office at IAMERS

2009 is election year at IAMERS. If anyone would like to run for office please submit your name, and the office you would like to run for, to Katie Moss-Solomon, Secretary of IAMERS. Please also copy your submission to Jeff Fall, Chairman of Ethics. In order to run for office, you have to be a member of IAMERS for at least the past 13 consecutive months. You must make your submission by March 1st. Your submission must be made in writing. Email is OK. Please make your submission to:

Katie Moss-Solomon – katie@expertmedicalsystm.com & Jeff Fall – jfsage@aol.com

Please submit requests for officer positions only. Board members, other than the officers, are appointed by the President. Questions – 201.833.1157.



IAMERS News & Information

- Please contact us by the 20th of January, if you have not received your tickets to the IAMERS reception at Arab Health.
- If you are planning on exhibiting at any of the shows noted at right, let us know. We will put your booth number in the Newsletter, at the appropriate time.
- Please let us if you can help on a committee. There's plenty to do in areas such as marketing. The more members that can help, the more we can accomplish. If there is something you would like to do for the association, let us know.
- If you have not paid your IAMERS dues for 2009, please pay your 2009 dues as soon as possible.

Comments and opinions are welcome.

Diana Upton
201•357•5400

2008 IAMERS Board of Directors

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Contact IAMERS @ 877•304•2637 or 201•833•1157

Important Dates & Events 2009

ECR – Vienna, AT • 6 – 10 March 2009
IAMERS ECR Reception • Sunday 8 Mar 09
Grand Hotel Wien – Kärntner Ring 9

IAMERS 16th Annual Meeting
San Juan, PR • 30 Apr – 2 May 09
InterContinental Hotel – 5961 Isla Verde Ave.

AAMI – Baltimore, MD • 6 – 8 Jun 09
Baltimore Convention Center
IAMERS booth # 812

SNM – Toronto, CA • 13 – 17 Jun 09
IAMERS booth # TBA

AHRA – Las Vegas, NV • 9 – 13 Aug 09
Mandalay Bay Hotel
IAMERS booth # TBA

IAMERS European Meeting • 10 – 12 Sept 09
Rome, IT
Location TBA

MD Expo – Nashville, TN • 23 – 26 Sept 09
Marriott Renaissance Downtown

EANM – Barcelona, ES • 10 – 14 Oct 09

RSNA 2009 – Chicago, IL • 29 Nov – 3 Dec 09
IAMERS booth # TBA
IAMERS RSNA Reception • Monday 30 Nov 09
InterContinental Hotel – Michigan Ave