



## Insights on Health

*A bi-weekly newsletter*

Welcome to the August 22, 2008 issue of Health Industry Insights' newsletter, **Insights on Health**. We publish every two weeks, examining recent events and offering opinions on key trends in the healthcare and life science industries. Please feel free to forward this newsletter to colleagues or others who might find it relevant.

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### **FDA Complete Response Letters: Less Information, More Hype Ahead**

*By Alan S. Louie, Ph.D.*

Prior to August 11, 2008, the FDA had 3 response options to a new drug submission: approved, approvable or non-approvable. From a public perspective, this could be simplified to mean (respectively): new treatment option, possible new treatment option sometime in the future, or failed effort with nothing new coming. From a biotech company stock value perspective, this was likely to mean (also respectively): significant increase in valuation and income on the horizon, delays and loss of value from 10 to 90% depending on follow-on CEO interpretation of the letter, or dead in the water with more than 90% loss in valuation. Large pharmaceutical companies are expected to see a dampened impact, depending on the proportional impact. The FDA decision to change their reporting to one of two options, either approved or complete response, decreases the knowledge available to the public for new drugs. Since the contents of both approvable and non-approvable letters are already proprietary, the public's insights are limited as described above. Complete response letters are also proprietary, leaving the public with even less information. We are now increasingly dependent on interpretation of the CEO message, which typically presents an overly rosy picture of a drug's promise, a situation likely to marginalize failed drugs and reduce the credibility of promising approvable drugs.

The FDA maintains that the new reporting is a more consistent and neutral response to an application that doesn't meet the requirements for approval. In responding to unproven criticisms that the FDA has responded with increasing numbers of "approvable" letters (potentially to respond to their inability to review submissions within PDUFA guidelines), this new action eliminates the problem by eliminating the metric. This also seems consistent with the FDA's abdication of blame for reduced drug approvals despite common sense expectations for increased safety for new drugs and the additional efforts needed to fulfill these enhanced requirements.

So what happens next?

- Public demands for public disclosure of letters will be denied on the grounds of company confidentiality.
- Consumers will have less definitive information available to assess whether new therapeutics are expected.
- Drug companies will be less transparent to the financial markets, reducing access to capital and creating intense hyper-scrutiny over CEO responses to complete response letters. A wrong word or personal inflection in the response can be expected to result in strong negative market overreaction.
- New drug development will be further slowed.



In these increasingly data intensive times, the FDA needs to be more transparent in their efforts, not less. As the primary gatekeeper to the future of healthcare in the United States, the FDA has chosen to be passively reactive, resulting in high uncertainty and significant delays for innovators looking to bring new medical solutions to consumers. While the problems and the solutions clearly do not lie solely with the FDA, more definitive leadership with clear requirements and objectives is needed to drive progress. This includes clear recognition of the acceptable limits around drug safety (especially increasing public awareness that there is no such thing as a completely safe drug), better guidance on criteria for follow-on drugs (i.e., determining whether incremental improvement intended to extend patent life provides significant benefit to consumers to be justified), defined metrics necessary to advance new novel therapeutic approaches into human testing (e.g., what data is specifically needed to begin stem cell trials), better defined limits and rules around DTC advertising (define education/sales limits), and more. Instead of hiding behind complete response letters and announcements that the lack of new drugs isn't its fault, the FDA needs to take the bull by its horns, if it ever hopes to begin a path towards sustainable healthcare.

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## **Field Sales Play Pivotal Role in eDetailing Success**

**By Eric Newmark**

Early eDetailing initiatives achieved little success because companies mistakenly delivered the same information in electronic form that physicians had already been receiving through traditional channels. Simply digitizing information into multimedia form did not present any additional value add for doctors. Over the last several years, the integration of eDetailing and CRM has given pharmaceutical companies the ability to customize messaging based on physician segmentation, leading to the delivery of personalized content more closely aligned with physicians' wants and needs. This integration point has become central to closed loop marketing (CLM) tactics employed by today's pharmaceutical companies.

Beyond delivering customized messaging, it is vital to get sales reps on board with the technology at a very early stage. Reps must feel excited about the technology and some ownership for its success. Getting sales reps acquainted with the technology at the final hour, or attempting to mandate its adoption are both mistakes that can instantly lead to project failure. Sales reps already have minimal face time with physicians and are lucky to get in a few meaningful words during in-person interactions. Mandating that reps deliver a set number of eDetail presentations per week immediately sends the wrong message to sales reps (that their company doesn't trust them to properly deliver the message themselves) and will be met with resistance. For example, one pharmaceutical rep recently interviewed explained how he used to play "at least 3 of 5" weekly mandated eDetailing presentations to his dog during off hours, since his company had no visibility to who was watching the presentations and finding the opportunity to play it more than twice per week for a physician was unrealistic. An extreme example? Yes, but an unfortunate reality of trying to force technology.

Sales rep utilization plays a large role in determining eDetailing success, and reps are only going to adopt technology that they personally feel makes their job easier, saves them time, or will increase their compensation by driving increased prescriptions. Consequently, eDetailing needs to be positioned to sales teams as another tool in their arsenal that can benefit *them*. For example, many doctors won't give a sales rep more than 10 seconds to sign for samples, but when the rep is able to capture the physician's attention with a flashy video displayed on the rep's handheld while the physician signs, it might provide the rep an extra 15-20 seconds to quickly mention a few facts from a recent clinical study while the doctor's attention is captured by the video. Scenarios like this represent small wins that sales reps will appreciate and will result in their being more appreciative of the technology.

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## Lowering Healthcare Payer Profits + Increasing CDHP adoption = a Trigger Toward Micro-Consumerism?

*By Janice Young*

Consistent with broader economic trends, healthcare payers have reported lower profits throughout 2008. According to an analysis by the Executive Report on Managed Care, as of second quarter 2008, the profits of the top six US healthcare payers dropped on average 37% for the year. Simultaneously, a survey by United Benefit Advisors finds that, among employers surveyed, consumer-driven health plan adoption had increased by 43% from last year, comprising nearly 13% of all plans offered by employers. Healthcare payers have also reported significant expansion in product portfolios in the past year to include a plethora of population-segmented plans (e.g., "young-healthy" programs) as well as new products targeted at the individual and senior markets.

Pinched by lowering profitability and relatively poor economic projections, healthcare payers must increasingly understand their customers' needs, wants and motivations to develop and execute profitable programs and services. Consumers, on the other hand, will demand the product and service specialization that they have come to expect from the retail and financial services industries. In the next five years, product and program focus will begin to shift from population-based initiatives to "micro-consumerism" initiatives. These initiatives will use a variety of new information technologies to collect information about individual consumer desires and behaviors and to use this information to develop much more personalized and customized products, services and interactions delivered through an increasingly wide variety of channels. The bottom-line goal: manage and increase profitability through better healthcare outcomes and improved consumer satisfaction.

If the healthcare market were consistent with retail and financial examples, healthcare payers might be expected to use analytics and communications technologies to identify and promote services to profitable individuals or groups, while seeking to deter coverage and services for others. The healthcare industry is, of course, always dissimilar from other consumer industries by regulation and increasingly by the growing discussions of mandated universal coverage.

For healthcare payers, the "micro-consumerism" challenge is also different from other industries. Information technologies will be used not just to identify and keep the top consumers happy, healthy and satisfied; but, perhaps more importantly, to understand and focus products and services to improve performance of the most expensive and difficult populations and individuals.

Either way, look for the "micro-consumerism" strategy to take hold and a significant expansion in 2009 and beyond of investment and adoption of related technologies across the enterprise and specifically including analytics, communications, integration and sales/marketing initiatives.

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## Ambulatory EMR/EHR Vendor Consolidation Continues

*By Marc Holland*

In our 2008 Predictions, published in January, and in our February 2008 report: "EMRs, Their Current State and Future Direction, Part 2: Ambulatory Care" (#HI210696), we predicted two trends for this year: vendor consolidation and an increased emphasis by vendors on hosted (SaaS-based) EMR/EHR solutions.

Consolidation, of both vendors and products, are a natural consequence of market maturation. The ambulatory EMR/EHR market is no exception. Long term, the market cannot sustain the more than 100 vendors currently offering an ambulatory EMR/EHR or components thereof. Small startups have



traditionally been the source of innovation in healthcare IT, as they have been in many other fields of endeavor, but as markets mature, consolidation follows. Most small firms lack the scale to compete in expanding markets and mergers, acquisitions or failures ultimately thin the ranks. In our report, we predicted considerable M&A activity and departures over the next 12-24 months, with much of the consolidation consisting of mergers between vendors with strong practice management products but weak or no EMR products and vendors of EMR products that lacked complementary practice management modules. We also predicted the rise of hosted solutions.

While the pace of consolidation has not been as brisk as expected, there have been several. The most visible of these was the merger of Misys and Allscripts, which was announced in March and is soon expected to close. Numerous hosted EMR/EHR solutions, including products from athenahealth, iMedica and Misys, have been introduced into the market this year, as well (notwithstanding iMedica's current spat with Misys over their agreement to remarket iMedica's product as Misys MyWay).

Over the past several weeks, Noteworthy Medical Systems, Cleveland, OH, has proven "noteworthy" with respect to both of these predictions. This week, it was announced that Noteworthy, a vendor of ambulatory EMR software, has acquired ChartConnect Inc., Yakima, WA, bringing Noteworthy not only increased market share and a more national presence, but also a more robust electronic prescribing module to complement its existing web-enabled product suite. ChartConnect serves about 200 practices with 1,100 providers and 3,700 total users. When the acquisition closes, Noteworthy will serve more than 1,200 practices with 5,700 providers and 12,000 users. On August 5, Noteworthy acquired Phoenix-based MARS Medical Systems Inc., which had previously been a strategic partner of Noteworthy. MARS' product line consisted of a remotely hosted practice management system that was often implemented alongside of Noteworthy's EMR/EHR solution.

Established multi-segment vendors have built their current market positions in the ambulatory EMR segment through acquisitions (e.g., GE's acquisition of Millbrook, IDX and MedicaLogic; McKesson's acquisition of Practice Partner – formerly known as Physician Microsystems – and Sage Software's acquisition of Emdeon – formerly Medical Manager – are prime examples). Microsoft, which has frequently touted SaaS as key to the future of the software business, has already made two forays into the EMR application space through its acquisitions of Azyxxi and Global Care Solutions.

There are, literally, dozens of ambulatory EMR vendors with viable products but limited market share and revenue streams. The market is simply too fractured, and too diverse, for small companies to mount effective national marketing campaigns. Larger companies, which possess the marketing "muscle," budgets and brand name recognition among physicians, will be the likely winners.

As summer ends, the pace of business will pick up again. We expect more such "noteworthy" events come fall.

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## **More Data Than the Human Mind Can Handle?**

***By Judy Hanover***

Earlier this August, the Institute of Medicine's Roundtable on Evidence-Based Medicine published its annual report, titled *Learning Healthcare System Concepts v.2008*. In the report, the Roundtable presents an update of its progress on examining and developing recommendations related to the role of clinical research and evidence in the practice of medicine. The goal of the Roundtable is to foster a "learning healthcare system," defined as one "in which each patient care experience naturally reflects the best available evidence, and, in turn, adds seamlessly to learning what works best in different circumstances." (<http://www.iom.edu/CMS/28312/RT-EBM/56903/57305.aspx>, p. iii)



The report highlights many issues confronting the U.S. healthcare system, with an emphasis on issues surrounding medical decision-making. The report cites the growing volume of knowledge and new diagnostic and treatment options, alongside the expensive, time consuming and limited research process we use to demonstrate clinical safety and efficacy, as providing an impractical challenge for providers to navigate. The growing volumes of data and lack of clinical effectiveness research makes it difficult for providers to select the best care options for their patients, let alone consider the cost and value of different options. In one particularly revealing statement, the authors write "... the average clinical encounter already requires a health provider to manage more variables than would be considered reasonable given what is known about the capabilities of the human mind (p. 5)." More data than the human mind can handle? Their point is not that providers can't handle all the data, but that we haven't organized the data or done the analysis of clinical effectiveness that will allow providers to apply it to clinical practice. A "learning healthcare system" is needed to turn all of this data into actionable information for providers.

Not surprisingly, the potential solution proposed repeatedly in the report is the use of electronic health records and advanced analytics. Tools are necessary to collect all the data and conduct analysis of safety and efficacy, estimate and manage risks, consider cost and value and track the results of interventions, among other considerations. Their role in improved healthcare decision making is yet another of the myriad benefits to be seen from electronic health records and analytics tools. Electronic health records clearly have the short-term potential to reduce medical errors and improve the quality of care, but this is clearly only the beginning of their potential benefit to the U.S. healthcare ecosystem. For more information about Health Industry Insights' research into electronic health record and analytics technologies, please contact me at [jhanover@healthindustry-insights.com](mailto:jhanover@healthindustry-insights.com).

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## **WellNet's Point to Point: A New Platform Combining Health Data Management and Social Networking**

***By Lynne A. Dunbrack***

On August 18, 2008, two Maryland companies, Health Interactive and WellNet Healthcare, jointly announced the launch of Point to Point. Developed by Health Interactive, the new technology platform combines the medical and prescription data management services offered by WellNet to health plan sponsors with a social network to connect consumers with their providers and WellNet's care managers. Using Point to Point, plan sponsors will have more immediate access to deidentified information about their medical and pharmacy claims expenses and their drivers (e.g., specific chronic conditions, a catastrophic case).

But what sets Point to Point apart from other health data management firms that provide predictive modeling tools – which enable plan sponsors to be proactive rather than reactive to spiraling claims expense – is that the platform is also made available to consumers. Consumers will be able to create a "social network" or directory of their providers, including PCPs, specialists, health and wellness coaches, and pharmacies, and communicate online through secure email or instant messaging channels. Consumers can also request via these same channels assistance from WellNet's care coordinators to refer them to specialists whom they can then add to their network. For example, the demonstration on the Point to Point Web site (<http://pointtopointhealthcare.com/>) shows Jane Doe asking the care coordinator nurse to refer her to a cardiologist. The nurse, acting as "a health care concierge," calls the office to make an appointment on Jane's behalf and updates Jane's Point to Point calendar. In addition to creating connections with providers and being able to communicate with them through secure channels, consumers can also search for health information content from MedlinePlus and receive alerts. Examples of alerts include a notice that a prescription or lab result is ready, information about a potential adverse drug reaction, or a request to contact their physician. Consumers also have access to their own medical and prescription claims expense information.



Conceptually, Point to Point's value proposition benefits multiple stakeholders – plan sponsors/employers, consumers, payers and providers – by connecting them to a single platform that provides a comprehensive view of the consumers' medical and prescription claims activity. Improved access to information and improved communication will facilitate the delivery of optimal health care. Furthermore, studies have shown that consumers want to communicate with their providers and obtain healthcare services online, just like they do in other facets of their lives. Engaging consumers to proactively manage their health not only improves their outcomes, but also reduces healthcare expenses.

The challenges facing Point to Point are the same challenges facing other organizations who offer portals for physician-patient communication, health and wellness coaching, health records aggregation and health information. While patients may want to communicate electronically with their providers, providers may find this new communication channel helpful or a hindrance. "How will these patient communications fit into the practice workflow?" "Will I get paid for them or do they become yet another uncompensated time sink? What about medical liability?" Provider education and recruitment to create a critical mass of connected providers will be paramount to successfully engaging consumers because they recognize their providers. Privacy and security concerns will always play a role in inhibiting some consumers from going online despite ardent assurances that the application is HIPAA-compliant and lives up to the same security standards of online banking. Unfortunately, too many consumers have heard about or experienced first-hand financial security breaches, as well as privacy spills in the healthcare industry, so these claims may not assuage the Internet-wary consumer.

Like other recently announced platforms that aggregate consumer health information and connect stakeholders, such as Google Health and Microsoft HealthVault, widespread adoption of Point to Point by providers and consumers will take time as WellNet builds out the critical mass of connectivity. For more information about Health Industry Insights' research into physician-patient communications and analytics technologies, please contact me at [ldunbrack@healthindustry-insights.com](mailto:ldunbrack@healthindustry-insights.com).

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## Health Industry Insights Latest Research

Click titles below to view report summaries on our Web site -- clients may download full reports after logging in.

- [Capgemini Recognized for Life Science Industry Expertise](#)  
Document # HI213840 Published August, 2008
- [U.S. Healthcare Payers and Vendors in the International Market: An Export/Import Opportunity](#)  
Document # HI213756 Published August, 2008
- [Intel Receives FDA Clearance for New Remote Patient Monitoring Device](#)  
Document # HI213743 Published August, 2008
- [The Practical Faces of Translational Research: Dana-Farber Leads the Way](#)  
Document # HI213727 Published August, 2008
- [Checking in on HIPAA Enforcement](#)  
Document # HI213722 Published August, 2008



- [Healthcare Provider Industry Short List: Ambulatory Electronic Health Records and Electronic Medical Records](#)  
Document # HI213204 Published August, 2008
- [A Blog a Day Keeps the Doctor Away? And Other Effective Blog Strategies](#)  
Document # HI213159 Published August, 2008
- [Life Science Buyers Guide: Manufacturing and Supply Chain IT Outsourcing](#)  
Document # HI212871 Published August, 2008
- [Additional Health Industry Insights Research](#)

## In the News

### News Mentions

Health Data Management (8/11)  
*Hospitals, Health Systems Create Own Health Data Networks*  
Marc Holland

SureScripts Rx Hub (8/4)  
*Healthcare Provider Industry Short List*  
Judy Hanover

Health Data Management (8/1)  
*The Hospital as the Network Hub*  
Marc Holland

Pharmaceutical Commerce Magazine (August edition)  
*Usability is the Focus of Latest Sales Force Automation Systems*  
Eric Newmark

## Events

### Web Conferences

[Transforming Pharmaceutical Sales and Marketing through Offshore Business Intelligence \(BI\) Services](#)  
Aug. 26, 2008 11:00 a.m. US Eastern time  
A web conference by HCL Technologies, featuring Eric Newmark

[Data Management... The Promising Future](#)  
September 9, 2008 2:00 p.m. US Eastern time  
A web conference hosted by Health Data Management, featuring Marc Holland

### Archived Web Conferences

[Manufacturing and Supply Chain IT Outsourcing: The Life Science Buyer's Guide to Vendor Selection](#)  
Presenter: Eric Newmark. Recording and slides available.

[Health 2.0—The Transformation to Online Care](#)  
AHIP Replay Webcast featuring Lynne Dunbrack

[2008 Archived Web Conferences](#)



## ***Industry Events***

### [Healthcare Conference 2008, France](#)

Sept 18, 2008

Paris, France

### [CIO Healthcare Summit](#)

Sept. 10-12, 2008

Dallas, TX

### [Life Sciences Technology Insight](#)

Sept 14-16

Philadelphia, PA

### [Center for Connected Health](#)

### [Symposium 2008 at the Conference Center at Harvard Medical](#)

Oct. 27-28, 2008

### [Additional Events](#)

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