Award-Winning Business News Articles

Explanation of the enclosed:

The enclosed letter accompanies two articles I submitted as one piece to the Newsletter Publishers Foundation Journalism Awards.

These two articles together, written for my publication, Inside Healthcare Computing, won an award for investigative reporting in the 1996 competition.

The letter explains the submissions, but may not be clear on authorship. I wrote the 1993 piece. Shortly thereafter, I hired Suzanne Corrales as the principal reporter for Inside Healthcare Computing. Under my supervision, Suzanne researched and wrote the first draft of the 1995 followup article. I rewrote it into its final form.

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NPF Journalism Awards
Newsletter Publishers Association
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Dear Newsletter Publishers Foundation:

In April, 1995, a Los Angeles Times reporter, Josh Meyer, pursuing a story about a costly failure of Los Angeles County's hospital computer system, made a California Public Records Act request. In the response, he came across an earlier request for the same information, made by an organization called "Inside Healthcare Computing."

Meyer had no idea what "Inside Healthcare Computing" was. But he noticed that it was not far away in the farm town of Oxnard, the Strawberry Capital of California. So he called to ask who we were, and why we'd been interested in those documents.

Meyer's instincts were perfect. Inside Healthcare Computing was just what he needed--a little-known newsletter which had already published the complex story he was wading through.

Even better was his timing. We had something much, much hotter for him.

Ten days later, Meyer's byline appeared over a national news story which his own Washington bureau, and all the Washington papers had missed: that the Food and Drug Administration had recalled the most widely-used blood bank computer software in the United States, saying it was laced with bugs that could cause the release of AIDS-tainted blood--and that the vendor, Western Star, rather than have its 200 blood bank clients install fixes, was dragging its feet. Here was a story of bureaucratic inaction and of a company accused of putting its profits ahead of its duty to warn hospitals of a potentially life-threatening situation.

The AP picked it up, and it ran in newspapers all over the U.S. Meyer and the Los Angeles Times got the kudos.

However, that little newsletter from Strawberryville, Inside Healthcare Computing, had not only given Meyer the tip--it had already published its own story well before the L.A. Times. In addition, the IHC editorial staff had given Meyer copies of 150+ pages of key FDA documents documenting out the core of the story. Also, the trade newsletter's editorial staff had also given Meyer
a layman's walk-through of the complicated technical issues involved.

In fact, we'd been following it for two years:

Acting on a tip in early 1993, Inside Healthcare Computing had obtained FDA documents alleging that there were serious bugs in the Western Star software. Our March 8, 1993 story (enclosed) reported that FDA concluded that the software bugs could cause the release of AIDS-tainted blood--but did nothing beyond warning the vendor to fix it--and that the vendor had responded with what appeared to be utter scorn for the regulators.

Inside Healthcare Computing had then FOIA'd FDA regional offices for reports on all other blood bank computer system vendors. The other vendors had been inspected, but none had set off alarms with the FDA as Western Star had.

In addition, before and after publishing our 1993 story, IHC interviewed users of the system all over the U.S. These interviews nailed down the fact that the vendor had never told users that there were serious bugs, or that the FDA had ordered fixes. Our interviews drew interest from one quarter-Western Star, which threatened to sue.

The editorship of Inside Healthcare Computing passed from Bill Donovan to Suzanne Corrales in late 1993.

In early 1995, Ms. Corrales began working on a followup, and learned that FDA had again inspected Western Star. She pried documents from FDA showing that Western Star had not fixed the allegedly deadly bugs, and that FDA had issued a recall for the software--without warning the public, the hospitals, or anyone.

We believe that this coverage merits an award because it exemplifies these characteristics of investigative reporting:

1. Cultivation of sources. Our location places us at a distinct disadvantage in competing against the hundreds of Washington, D.C,-based news media that should have been interested in this story. We learned about and kept up with these events from a distance by finding and cultivating the right sources.

2. Intelligent presentation of complex issues. This story dealt with the intricacies of a big computer system, with complicated bureaucratic regulations, and with medical terms. No one was willing to talk to us, much less explain anything. We think we managed to turn these three bodies of arcane jargon into plain English.

3. Overcoming obstacles and risks. Reporting on business carries risks and hurdles which are not present, or are smaller, when reporting on government. One's subjects virtually always have the money to sue; they usually have a substantial size advantage, and one never knows when a company made decide that a lawsuit is its only option to protect its business reputation, regardless of merit. This was a story no one wanted to talk about. FDA officials were scared. Western Star threatened legal action. Users of the systems had an obvious desire to have the whole story quietly go away, as their blood banks would be the first ones liable if any harm were discovered.

4. Results and outcomes. The allegedly dangerous bugs in the Western Star system were repaired under the glare of publicity. The Los Angeles Times received credit from peers for a good national news story that the Washington press corps missed. And Josh Meyer's byline is more prominent these days in the L.A. Times.

5. It's a prominent story. We published it first, and helped a large, prominent daily newspaper find its way through its later story. The Los Angeles Times, Meyer told us, has a policy against giving credit to small news organizations such as ours.

For the reasons described above, we submit two stories from Inside Healthcare Computing:

- **"FDA Orders Blood Bank Software Vendor Western Star To Make Fixes," published March 8, 1993, and**
- **"FDA Recalls Blood Bank Software," published April 3, 1995**

as a single entry in the Newsletter Publishers Foundation Journalism Awards category, "Best Investigative Reporting."

Please note: we have also submitted this article and a related article as an entry in another category, "Best Spot-News or Exclusive Single-News Story," with a similar cover letter.

Sincerely yours,

Bill Donovan
Publisher

From the March 8, 1993 issue of Inside Healthcare Computing, a biweekly newsletter on healthcare information systems

FDA Orders Blood Bank Software Vendor Western Star To Make Fixes

Both Sides Claim Win in First Action vs. a Software Firm

By William Donovan

Last September, the U.S. Food and Drug Administration went to the brink of harsh legal steps which might have included ordering a recall of the software than runs blood banks in 200 hospitals and other sites. The agency held off only after the vendor sent fixes for what FDA says were serious bugs. FDA's letter appears to indicate it felt that at least one alleged bug might cause tainted blood to be mislabeled as normal.

The case is believed to be the first of its kind under a 1990 FDA policy decision to include blood bank software under the full weight of medical device rules. It signals that FDA is serious about regulating software. And the series of steps FDA took are a glimpse of what could happen to others after the FDA inspector shows up. Many vendors and others believe that, as other kinds of clinical information systems proliferate and become more complex, they will eventually fall under the kinds of rules to which only blood bank software is now subjected.

Hospitals could be affected by regulation of software as medical devices primarily in two ways: (1) users of medical devices are required to send reports to the vendor on problems, and the vendor must keep a file of those reports for FDA inspectors; and (2) if FDA finds serious problems, the software could be suddenly recalled.

The vendor was Western Star of Lake Oswego, Ore. Its 200+ clients are believed give it the largest client base of any blood bank software vendor. (the software is sold stand-alone and with Citation lab systems.) Its president, John Tortorici, in an interview last week, sharply disputed FDA's view that there ever were problems. He said the changes were done only to get FDA off his firm's back. He declined to discuss the detailed list of the alleged problems cited in the FDA letter, saying the issue is dead.

That's not the view of the FDA. A Seattle FDA enforcement official said FDA could still order the software recalled if it is unsatisfied with the results of a followup inspection (FDA won't say when). The story began when an FDA field investigator, Norman Wong, showed up for a routine inspection at Western Star's headquarters April 20, 1992.

Wong saw numerous "Program Problem Requests" (PPRs)--forms which users must file with vendors if they think they see problems or faults in medical devices. One user had filed 74 such complaints from January 1991 to April, 1992.

On April 30, Wong gave Western Star his Form FDA-483 Inspectional Observations, describing numerous alleged problems. Western Star wrote to FDA June 16, 1992, saying it intended to act on all the Form 483 concerns.

It is not clear from the documentation and from interviews what transpired behind the scenes, but two months later, on Aug. 17, FDA issued what is called a "Warning Letter," ordering Western Star to notify FDA within 15 working days of "specific steps you have taken to correct the noted violations and prevent their occurrence," adding that FDA "is prepared to invoke regulatory sanctions under the law. These include seizure and injunction."

A Warning Letter is "the last shot before more serious legal action," said FDA Seattle District Office Chief Roger Lowell. FDA wouldn't have sent another warning before its next action, which could have been a recall, he said.

Tortorici said, "They (FDA) misunderstood the whole thing."

Not so, said the head FDA enforcement officer in the district, Joseph Baca. "We don't issue a warning letter unless we have a significant issue." He added, however, that FDA considers Western Star's response and software changes since the Warning Letter to be "satisfactory."

Excerpts from the FDA Warning Letter:

"General review of the Program Problem Requests (PPRs) received from users indicated that many software defects have been discovered by the end user after software changes were made by your firm...For example:"

"a. PPR 9042 notes a complaint reporting that (the software) changes permanent deferral status "P" of donors to normal status "N" for donors with positive serologic tests.
"b. PPR 8960 noted the system does not place units with positive test results into quarantine status when the data are automatically transferred from (blotted out in the copy we received) analytical test equipment.
c. PPR 9013 indicated that the (name blotted out) interface did not accept both identical duplicate repeat test results or test results below minimum values..."

FDA also cited alleged failure to detect and fix problems prior to distribution to users. "For example, between January 1991 and April 9, 1992, there were 74 PPRs generated by (name blotted out) identifying software defects in software that had been distributed."

According to the FDA letter, another user complaint said that two users can edit Western Star's Blood Bank Donor Management File at the same time. "If the first user enters a change to the file and exits before the second user finishes his/her update to the file, the second user's screen information overwrites the first user's entries, and the first user's entries are lost when the second user exits the file. This problem has been reported twice, but has not been corrected" (as of the Aug. 17, 1992 letter).

Also, FDA said not all affected users had received fixes; there was no method to ensure that the users actually installed fixes; and some problems in PPRs sent as early as 1989 had not been fixed. FDA alleged a number of additional problems in testing and documentation of the system.

From the April 3, 1995 issue of Inside Healthcare Computing (next page):

inside
HEALTHCARE COMPUTING

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FDA: 'Stop Using It'; Users: FDA's 'unrealistic'

FDA Recalls Blood Bank Software

The FDA has recalled four releases of the Western Star Lifeline blood bank software due to alleged defects. The recalls are classified as "voluntary recalls," meaning that the vendor is to enforce them.

FDA spokeswoman Monica Revelle said that users of a recalled software version have to stop using it. Their options include switching to another brand of software, upgrading to a non-defective version of Western Star's system, or discontinuing use of an automated system, she said. In recall situations, workarounds are generally not considered acceptable, she said.

Western Star disputes Revelle's views on the actions FDA requires.

FDA doesn't involve itself in the mechanics of a "voluntary" recall, Revelle said. However, FDA field inspectors will enforce the recall during their routine inspections of individual blood banks, she said. "We would be concerned if we found someone still using the recalled software," she said. FDA officials note that if they decide the recall was ineffective, they can take legal action to force the product off the market.

The upgrades were classified as recalls because they corrected serious programming defects, Revelle said. "We would not do this with an ordinary upgrade."

FDA officials directly involved in taking the recall action have declined to say exactly what prompted their apparently drastic action. However, they provided written documentation promptly in response to several IHC Freedom of Information Act requests. The documents suggest that FDA may have decided to classify the four releases as "recalls" because (1) some blood banks were still using old releases of the software with allegedly serious defects which FDA had already told Western Star to fix, and because (2) new user reports seemed to show that some old, identified defects had been passed on to some newer versions of the software. FDA says some of these alleged defects could result in release of tainted blood.

Western Star officials acknowledge that some software problems exist, but take a very different view of the actions required than Revelle's description. "With some recalls, it is necessary to bring the product back," said company consultant Rob Ngungu. "With software it is not like that." Ngungu, Western Star's full-time director of quality assurance and regulatory affairs, has worked in similar positions for other, more traditionally regulated firms.

Users said Western Star told them that the FDA wanted them on the most currently available version of Lifeline, and that they were supposed to use all applicable workarounds. A new version, 4.0d is due out in April, Ngungu said. The company said it disagrees with the FDA's decision to call the upgrades recalls. "None of these versions (4.0a, 4.0b, 4.0c) were released primarily to fix previous problems," Ngungu said.

Western Star President John Tortorici, in a letter to clients, offers another interpretation of FDA's action: "...we believe that all blood bank software vendors will be required to treat the release of future versions of their software as if the prior release or releases had been recalled..."

Lifeline is believed to be the nation's most widely used stand-alone blood bank systems. It is installed in approximately 250 American hospitals. (CAP TODAY October, 1994). Based on the FDA's account, most users will be affected by the recall.

The decision is controversial with both users and HIS consultants, who said the Lifeline software is no more problem-prone than many other systems on the market. LIS Consultant Dennis Winsten said FDA efforts in recent years have helped improve the quality of LIS software. But a recall forcing users to return to a manual system could cause the public more harm than good, he said.

No evidence seen of tainted blood releases

There is no evidence that there has been a reportable incident using Lifeline, Western Star said. Revelle agreed that "There have been no incidents" reported.

The recall is not related to the FDA's new registration and pre-market certification regulations for vendors of blood bank software, Revelle said. Those new rules were recently delayed by FDA.

FDA documents, obtained under Freedom of Information Act requests, say:

Defects in Lifeline releases 4.0a and 4.0c could result in violations of good manufacturing practice, while defects in releases 4.0 and 4.0b could result in the release of untested blood, blood that tested reactive, or blood that was collected from ineligible donors. In some cases, releases that corrected defects introduced new defects of their own, the FDA said.

FDA reports said the company didn't always adequately test new releases. Also, prior to the recall, Western Star provided users with upgrades and documentation, but didn't track whether they installed them, the FDA said. Release 4.0 was issued July 24, 1992; Release 4.0a, Jan. 7, 1993; Release 4.0b, Sept. 24, 1993; and Release 4.0c, March 4, 1994. A September, 1994, FDA inspection report said the company issued its notice to users about a problem in version 4.0b on March 28, 1994; and its notice to users about a problem in versions 3.1 and 4.0 on August 29, 1994. The notices imply that those versions were still in use on those dates.

The disputes between FDA and Western Star appear to have begun with user reports leading up to an FDA inspection in April 1992. The FDA inspector's report of the 1992 inspection alleged that two defects related to an automated interface used by a few blood banks with Release 3.0 of the software "CHANGES STATUS 'P' DONORS TO STATUS 'N' ON POSITIVE SEROLOGIC TESTS." ("P" means permanently deferred from use as donor blood; "N" means normal; capitalization is the FDA inspector's).

The consequence of this alleged defect, the FDA inspector's report claimed, was that "ANY POSITIVE UNITS INCLUDING HIV POSITIVE UNITS WILL BECOME AVAILABLE FOR TRANSFUSION UPON COMPLETION OF ALL REQUIRED TESTS." (Underlining and capitalization are FDA's.) These alleged defects were apparently addressed in Version 3.1, but the FDA inspector wrote, "there was no indication that the user was made aware of this major software bug, and its potential for the release of reactive HIV units." FDA issued Western Star a warning letter at the time, saying that recall was a possibility.

Don't be too alarmed: the alleged major defect described above was apparently fixed in Version 3.1. However, that report said users wrote FDA on other alleged defects in Version 3.1 which FDA said could also result in incorrect data on positive/negative blood screening.

On August 29, 1994--by which time Releases 4.0 through 4.0c had been issued--Western Star, in an FDA-required report to users, listed another company-described defect in Versions 3.1 and 4.0

which could change the status of blood from "D" (deferred) to "N" (normal). The references imply that some blood banks were still using Release 3.1, which was four releases old by then, and that the alleged defect had been carried over to Release 4.0.

FDA said there were 70+ required reports from users or Western Star staff to FDA on alleged defects or problems when it inspected in 1993, and that the number of these outstanding reports of alleged defects or problems had grown to 178 as of September 1994.

Western Star is publicly held, under the corporate name "Infostat Inc."

Western Star Has Made Many Efforts to Correct Defects

Western Star consultant Rob Ngungu said FDA's reports on alleged defects should not be taken as the last word. "They are just one inspector's opinion," he said. Moreover, FDA regulations have changed, so vendors are being held responsible retroactively for standards that did not apply to them at the time the system was released, he said.

"There has been a gradual and continued improvement on all the issues the FDA has raised," he said. "We are working closely with the FDA and we will continue to do so."

Blood bank information systems should be evaluated in the context of the way users implement them, said Norman Wong, one of three field inspectors who issued critical reports of Lifeline. Users may have systems that compensate for software deficiencies, he said. "You have to look at the whole picture," he said. (For user reports on the system, see following story.)

In that April, 1992 inspection report, Wong criticized Western Star for software defects relating to Lifeline Releases 3.0 and 3.1, inadequate software validation procedures, and failures to document good manufacturing practices. Western Star wrote back, attempting to explain some of the difficulties and promising to act on the rest.

Wong re-inspected in July, 1993. His report said it appeared that some defects that were to have been corrected in versions 4.0 and 4.0a hadn't been fixed, and that new ones had been introduced because Western Star was using inappropriate validation tests on its software.

His 1993 report noted "more than 70" uncorrected PPRs. PPRs are Program Problem Requests, which are given to the vendor by users and vendor employees, to bring software defects to vendor management's attention.

When two other FDA inspectors inspected in September, 1994, they found that Western Star had instituted a complaint classification system which the FDA had requested. Their report also indicated that a number of defects found in earlier software versions were corrected in Release 4.0c. Their inspection was less comprehensive than Wong's. FDA District Director Roger Lowell said their purpose was to determine whether the software should be recalled.

The inspectors noted that there were 178 outstanding PPRs, and seven new TARs or Technical Action Requests. TARs are notifications to users of software defects "which may adversely affect data integrity, control of components within the user facility, or quality of product," the FDA report said. Examples of TARs identified in Sept. 1994 FDA report are:

- TAR 45, which existed in all versions of release 4.0b, and was corrected in 4.0c. If two or more persons using the Change Unit Status program for a unit at the same time were to make a change to the unit, the change made would be that of the last person to exit the program and the status changes would be written to the history file of the unit, but not to the master file. Since units are released based on their master file status, "this problem could have allowed release of a quarantined unit."
- TAR 47 existed in all versions of release 4.0b, and affects autologous units, which may be tested only for blood type and Rh factor. "A cross-matched auto unit, (status X) which is later

intended to be crossed over for homologous use, would have the 'auto' attribute flag removed by the user." "The status of the unit was reverting to 'A' (available) rather than 'U' (untested--for those tests not originally performed on the auto unit)." "These units could be released for transfusion."

- TAR 48 applies to all versions of release 4.0c. Western Star gave it an 'A1' classification, meaning that the problem could lead to the release of an unsuitable blood unit without an alert warning from the system. If, while entering a blood type in a patient file, the user included a space, (eg 'A -' rather than 'A-') the program would not recognize the '-' attribute, and no alarm would sound if the blood type was not correct for the patient. A fix is available. With it, an alarm will sound if the blood type is not an exact match for the patient. However, the program will still accept spaces between the blood type and the attribute.
- TAR 49, issued Aug. 29, 1994, applies to some versions of releases 3.1 and 4.0. A donor's blood type, Rh factor and donor status ('N' for normal or 'D' for deferred) could be restored to what they were prior to testing of the units if the donor's registration or master file was open at the same time the test results were posted to the donor file. The problem could result in a previously normal donor with a positive test result not being changed to deferred.

Users Say Western Star Lifeline Is A Good System Overall

Users acknowledge that Western Star Lifeline system has some defects, but insist it is the best stand-alone system of its kind available. Their biggest concern: the amount of time and effort that will be required for them to validate version 4.0d, now that 4.0c has been recalled.

Western Star does not have a bad reputation among vendors blood bank software, said LIS consultant Dennis Winsten. "I haven't heard any real negatives about (the company)," he said.

Some users blamed Western Star's difficulties on the FDA, which, they said, is sometimes confused or unrealistic in its expectations. "Nobody understands what's going on," said one.

A possible example of mixed signals from the FDA: a user, who was recently inspected, said the FDA field inspector left her with the impression that "if you are live on the current release, you're OK." But FDA spokeswoman Monica Revelle implied more urgency, saying that the recall means "stop using the system." (See related story.)

FDA District Director Roger Lowell said the recall was initiated by the FDA in Washington, D.C., which reviewed inspection reports generated by the district office. Inspections of Western Star were initiated by user complaints, he said. Reacting to complaints by sending inspectors to evaluate the system was "business as usual" for the FDA, he said.

Three hospitals on a list of users of Western Star Lifeline said they're not users. One said he dropped the system three years ago because "there were problems." He declined to elaborate. Another discontinued Lifeline because of a merger with a hospital that used Cerner. A third said her hospital bought the system but never installed it. She declined to elaborate.

Here are three other user reports:

Ochsner Foundation Hospital, 381 beds, New Orleans, La.: blood bank spokeswoman Mary Murphy said Western Star has been "open and clear" in its communication about its problems with the FDA. Her understanding of the problem: "the FDA was not very happy with the records Western Star kept on its own (in-house) validation testing." She said the FDA may watch Western Star more carefully than it watches other companies because Western Star was the first blood bank software vendor to registered as a device manufacturer. "From a user standpoint, what the FDA is doing is good," she said.

Murphy said her hospital is on version 4.0c and reported one bug (TAR 48) to Western Star. The workaround? "I understand the problem and I am the only one who enters the data."

McKay-Dee Hospital, 347 beds, Ogden, Utah: Medical Technician Lori Baxter said she anticipates staffing problems arising from the transition to 4.0d. Her facility is one of seven in a system of blood banks, and she has been informed that unlike past updates, which could be done on a facility-by-facility basis, the 4.0d update will require simultaneously taking down the computers running the software at all seven locations. Therefore, instead of one consultant traveling to each facility for a day (followed by 10 days of debugging), each blood bank will have to donate one employee to help ensure the update proceeds smoothly.

Another problem: Baxter said that at least one defect has lived on uncorrected since the early 4.0 days. If a patient tests positive for a blood-borne disease, he or she is given a "Perm" rating (do not draw blood, permanently deferred). If it later turns out that the patient gave blood at the blood bank before the Western Star software was installed and under a different name, in order to merge the data field that was transferred to Western Star from the other system with the new data, the "Perm" label would have to be manually changed in the system to "Normal" and then manually changed back to "Perm" after the merge is complete. If a technician forgets to make the change, "you can have tainted blood in the system labeled 'Normal,' " Baxter said. As far as Baxter knows "they haven't fixed the problem in any of the upgrades."

In general, "I like the software a lot, although I didn't really until I compared it to other systems," Baxter said. "There's not much else out there."

A third user, who wished to remain anonymous, was also concerned about the time it takes to validate new versions. Moving from version 4.0B to 4.0C took only one day, but other upgrades required four full-time technicians to work a week to install correctly. In addition, this user was not informed by Western Star that the upgrades were due to a recall; she thought the company was just sending out routine upgrades.

"If I could find software that does the same things (as Western Star's) without the problems, I would go with it," she said. "But I don't know of any, and it would probably cost a lot."