using 17 kV [15] or 18 kV [11,12], but no one has yet examined the relationship between starting voltage and renal injury. Because we have previously shown a positive correlation between the voltage and lesion size [16], we hypothesized that as the starting voltage increases, the subsequent lesion sizes will increase. Accordingly, the present study was undertaken to determine if the starting voltage in a step-wise ramping protocol alters the size of the renal lesion caused by the SWs.

MATERIALS AND METHODS

The present study was carried out with an unmodified Dornier HM-3 lithotripter (Dornier Medical Systems, Kennesaw, GA, USA) located at Methodist Hospital, Indianapolis, IN, USA. This lithotripter has an 80 nF capacitor and a focal zone (F2) of about 1.5 cm diameter × 2.5 cm length. Refurbished spark plugs (Healthtronics, Kennesaw, GA, USA) were used for all experiments and were discarded after 1000 shots.

The experimental protocol used in this study was carried out in accordance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals and was approved by the Institutional Animal Care and Use Committee of the Indiana University School of Medicine. Nineteen female farm pigs, aged 7–8 weeks (Hardin Farms, Danville, IN, USA), were assigned to receive either 2000 SWs at 24 kV (a standard clinical treatment protocol, $n = 7$), 100 SWs at 18 kV followed by 2000 SWs at 24 kV ($n = 7$) or 100 SWs at 24 kV followed by 2000 SWs at 24 kV ($n = 5$). Both ramping protocols included a 3–4-min pause in SW delivery between the first 100 SWs and the remaining 2000 SWs to check targeting of F2. All SWs were delivered at a rate of 120 SWs/min. This protocol builds on a previously published study using 100 SWs at 12 kV followed by 2000 SWs at 24 kV [14]. That study was carried out with the same lithotripter, pigs of the same size and the same protocol as the present experiment.

At the beginning of the experiment the pigs were rendered unconscious with an i.m. injection of ketamine (15–20 mg/kg) and xylazine (2 mg/kg). They were then intubated and anaesthetized with isoflurane (1–3%) throughout the experiment. Sterile saline was infused through an ear vein at a rate of 1–3% of body weight per hour to maintain adequate hydration and urine flow. Surgical procedures for the placement of femoral artery and bilateral ureteric catheters have been described previously [17].

After a post-surgery acclimation period (2–2.5 h), the pigs were disconnected from the anaesthesia machine and transferred (unconscious) to the lithotripsy suite (a trip of ≈5 min) where administration of isoflurane anaesthesia was resumed. The pigs were then placed supine in the gantry of the HM-3 lithotripter. The pigs were positioned in the water bath (39 °C) so that one kidney could be exposed to the SWs. Positioning of each pig was accomplished by injecting a small amount of contrast medium (Renografin 60%, Bracco Diagnostics, Princeton, NJ, USA) through the ureteric catheter into the urinary collection system of the kidney to be treated. Using the positioning fluoroscopes of the lithotripter, F2 was located on a lower pole calyx of that kidney. The pigs were then treated with one of the three protocols listed above.

After SWL, each pig was returned to the surgical suite (once again disconnected from the anaesthesia machine for ≈5 min). At 4 h after the completion of the lithotripsy treatment, the kidneys were perfusion-fixed with 2.5% glutaraldehyde in 0.1 M sodium cacodylate buffer (pH = 7.4) as previously described [18]. After perfusion, the kidneys were removed and submerged in fresh fixative for subsequent determination of lesion size.

Kidneys used for quantification of lesion size were processed according to our previously published protocol [19]. Briefly, each kidney was cast, embedded in paraffin and serial sections were cut on a sliding microtome. A digital image of each section was captured and a computer-assisted segmentation technique was used to quantify the haemorrhagic lesion as a volume percentage of the total functional volume (FRV) of each treated kidney. The mean (SEM) was calculated for lesion size in each of the treated pigs.

The Kruskal–Wallis test, a nonparametric ANOVA for non-normally distributed data, was used for statistical analysis. Significant overall differences in the group medians were followed by *post hoc* comparisons adjusted by the Bonferroni method (comparing the standard clinical treatment protocol group, and the 18 kV and 24 kV voltage-ramping groups). The criterion for statistical significance was set at $P < 0.05$.

RESULTS

Figure 1 shows a digitized and pseudo-coloured cross-section of a kidney from each of the three treatment groups. Pigs from the standard clinical treatment group had a mean (SEM, range) lesion size of 3.93 (1.29, 1.15–9.37)% FRV. These kidneys had many areas of intraparenchymal bleeding. These sites were localized at the focus of the SW and involved both the cortex and medulla. In some cases, the haemorrhage extended all the way from the papilla tip to the capsule resulting in a subcapsular haematoma (Fig. 1). Kidneys from pigs in the 18 kV and 24 kV ramping groups lacked surface haematomas and contained very few areas of intraparenchymal haemorrhage. These damage sites were small, and were found almost exclusively in the medulla. The mean (SEM, range) lesion size for the 18 kV ramping group was 0.09 (0.01, 0.0–0.1)% FRV while the lesion size for the 24 kV ramping group was 0.51 (0.14, 0.15–0.87)% FRV. The mean lesion size for both of these groups was significantly smaller than the lesion size of pigs in the standard clinical treatment group ($P = 0.003$ for 18 kV, $P = 0.014$ for 24 kV).

DISCUSSION

These findings suggest that the beginning voltage is not the key determinant responsible for reduced lesion size in our ramping protocol. Starting voltages of 12 kV [14], 18 kV or 24 kV all produced the same degree of protection when compared with conventional nonramped SWL.

Studies over the last 20 years in our laboratory have shown that the application of 2000 SWs (24 kV, with a Dornier HM-3) to a juvenile pig kidney consistently produces a morphological lesion that averages 4–6% of the FRV [14,16,20]. Recently, Willis *et al.* [14] reported that one can 'protect' a kidney, i.e. reduce tissue injury, by treating that kidney with a series of low voltage shocks before delivering a clinical dose of SWs. While the cause of the protection is unknown, several factors could potentially trigger the response; e.g. the number of SWs given at the beginning of treatment, the starting voltage of the SWs, and the time interval between the SW applications.

The SW number was tested when Willis *et al.* [14] reduced the initial treatments of low voltage (12 kV) SWs from 2000 to 500 in one

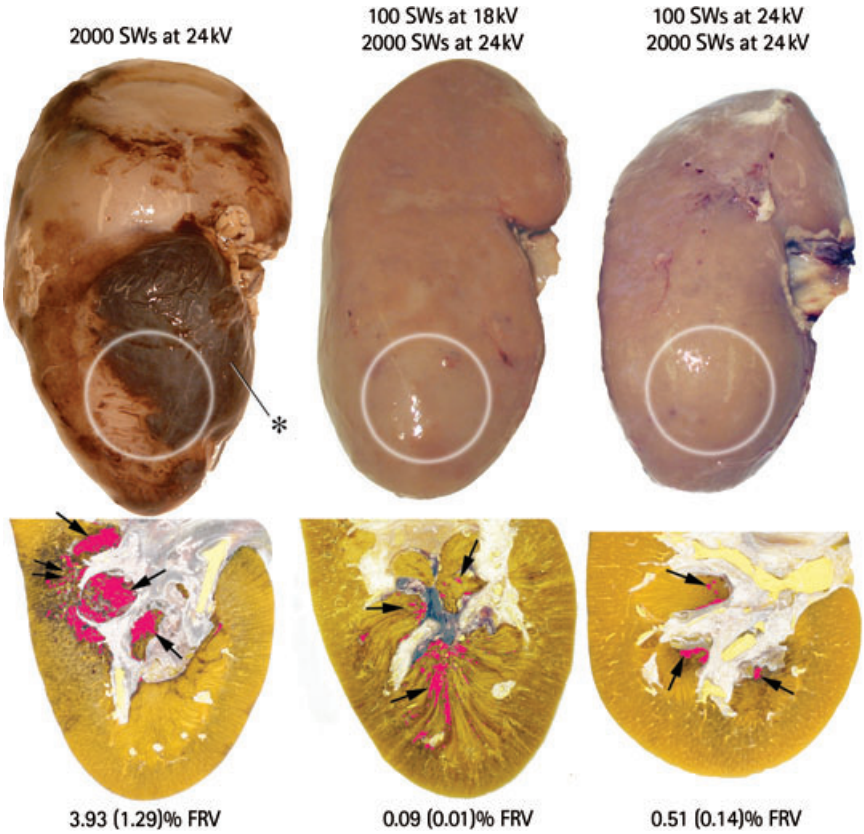
series of experiments, and then to 100 in another series. Similar protective responses occurred in each instance, indicating that if a threshold exists for the number of SWs needed to trigger the protection, it must be ≤100. Certainly, further study will be needed to determine if <100 SWs will still invoke tissue protection.

The second potential factor, starting voltage, was examined in the present study. Previous experience has shown us that tissue injury increases as treatment voltage increases [16]. In fact, we have shown that lesion size can increased 20-fold with only a doubling of SW voltage (12–24 kV) [16], and this led us to hypothesize that as the initial ramping voltage was increased the size of the renal lesion would also increase. However, the data showed that protection was comparable whether the treatment started at 12 kV [14], 18 kV or 24 kV. This suggests that, as a starting voltage of 24 kV was as effective as 12 kV at preventing renal injury, voltage ramping per se is not solely responsible for limiting lesion size. What mechanisms initiate the protective effect and how these mechanisms work to reduce lesion size are unknown. Recent work by Handa *et al.* [21] suggests that an increase in renal vascular resistive index, presumably from constriction of renal blood vessels during SWL, is involved in mediating the protective response, but these findings tell us nothing about what initiates the response.

The present findings support the rationale for using a voltage-ramping protocol in clinical SWL, as step-wise voltage ramping (from low to high voltage) improves stone fragmentation [10–13], and also limits renal injury. The present results indicate that a range of starting voltages (12–24 kV) can work to initiate the protective effect in the treated kidney. And, at least as conducted in the present experiment, voltage ramping causes less injury to the kidney than conventional nonramping protocols. Accordingly, clinical voltage-ramping protocols could be designed where the treatment regimens are optimized for stone fragmentation with the expectation that the ramping protocol will also initiate the protective response and limit injury. Clinical studies are needed to confirm this expectation.

The most intriguing and new implication arising from the present findings concerns,

FIG. 1. Gross appearance of kidneys treated with 2000 SWs at 24 kV (standard treatment), 100 SWs at 18 kV followed by 2000 SWs at 24 kV, or 100 SWs at 24 kV followed by 2000 SWs at 24 kV with an unmodified Dornier HM-3 lithotripter. The white circles show the approximate location of the SW focus (F2) on the lower pole of each kidney. Note that no sites of haemorrhage are evident on the kidneys using the one-step ramping protocol of 18 kV or 24 kV, while a large subcapsular haematoma (asterisk) is located on the kidney after standard treatment. Beneath the gross view of each kidney is a lower pole section showing the typical lesion found using each protocol and the average lesion size calculated in each group (expressed as the mean (SEM) of the percentage of the FRV). The lesion has been segmented and pseudo-coloured (red), so that the size of the SWL-induced injury can be appreciated. Single arrows point to papillae showing evidence of haemorrhagic injury. Double arrows indicate an area where the injury extended up into the cortex, a common finding in the kidneys from pigs after the standard treatment.



oddly enough, the 3–4-min interval of inactivity between the two applications of SWs. If starting voltage is not the factor that initiates the protective response, as appears to be the case in the present study, then the 3–4-min interval between the initial and clinical doses of SWs emerges as the principle factor that could be responsible for the protection. Otherwise, the 100 SWs at 24 kV ramping protocol, which includes the 3–4-min interval, should have produced a lesion at least as large as that without voltage ramping [14,16,20]. Although the present studies have not tested that the interval between SWs initiates the protection response, our data clearly suggest such a possibility. This, in turn, raises concerns for ramping protocols currently in use that do not include a resting interval between SWs applied at different energies. If a resting interval is critical for reducing SWL-related tissue damage, ramping protocols lacking this interval may predispose patients to unnecessary injury. Clearly, further study is needed to determine exactly if and how a period of inactivity between groups of SWs protects renal tissue from SWL-induced injury, but prudence suggests that brief resting intervals be added to clinical ramping protocols.

In conclusion, the present findings suggest that the initial voltage of a one-step voltage-ramping protocol for SWL does not correlate with renal damage. That is, voltage ramping

reduced the amount of renal injury when compared with nonramped SWL regardless of whether low or high voltage SWs were applied to start the ramping protocol. Our findings also suggest that the time interval between the first and second sets of SWs, as used in our experiments, may initiate the response that limits the renal injury caused by SWL.

ACKNOWLEDGEMENT

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CONFLICT OF INTEREST

None declared. Source of funding: NIH grant.

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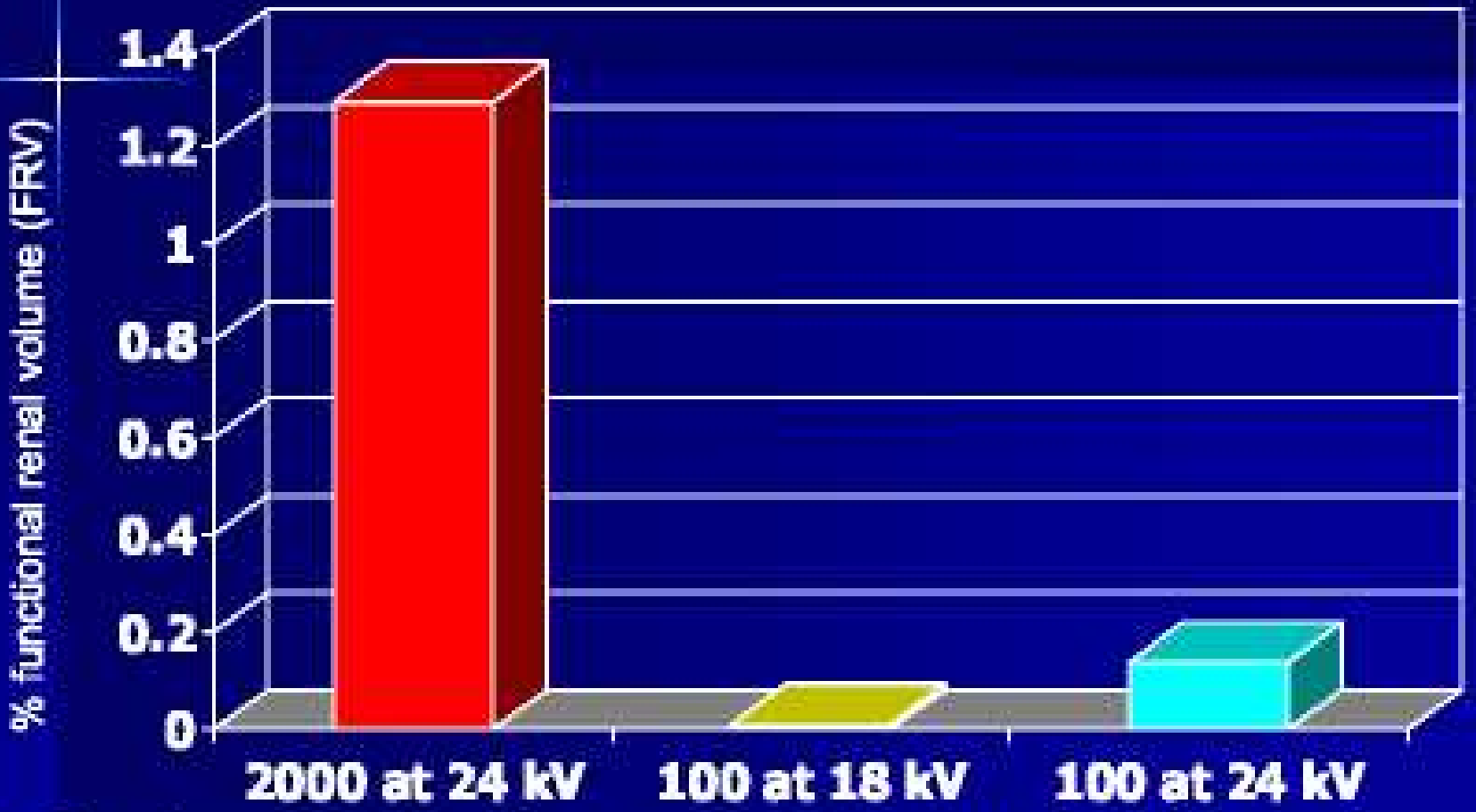
Abbreviations: **SW(L)**, shock wave (lithotripsy); **FRV**, functional renal volume; **F2**, focal zone.

Exhibit 6

Pause for the Cause

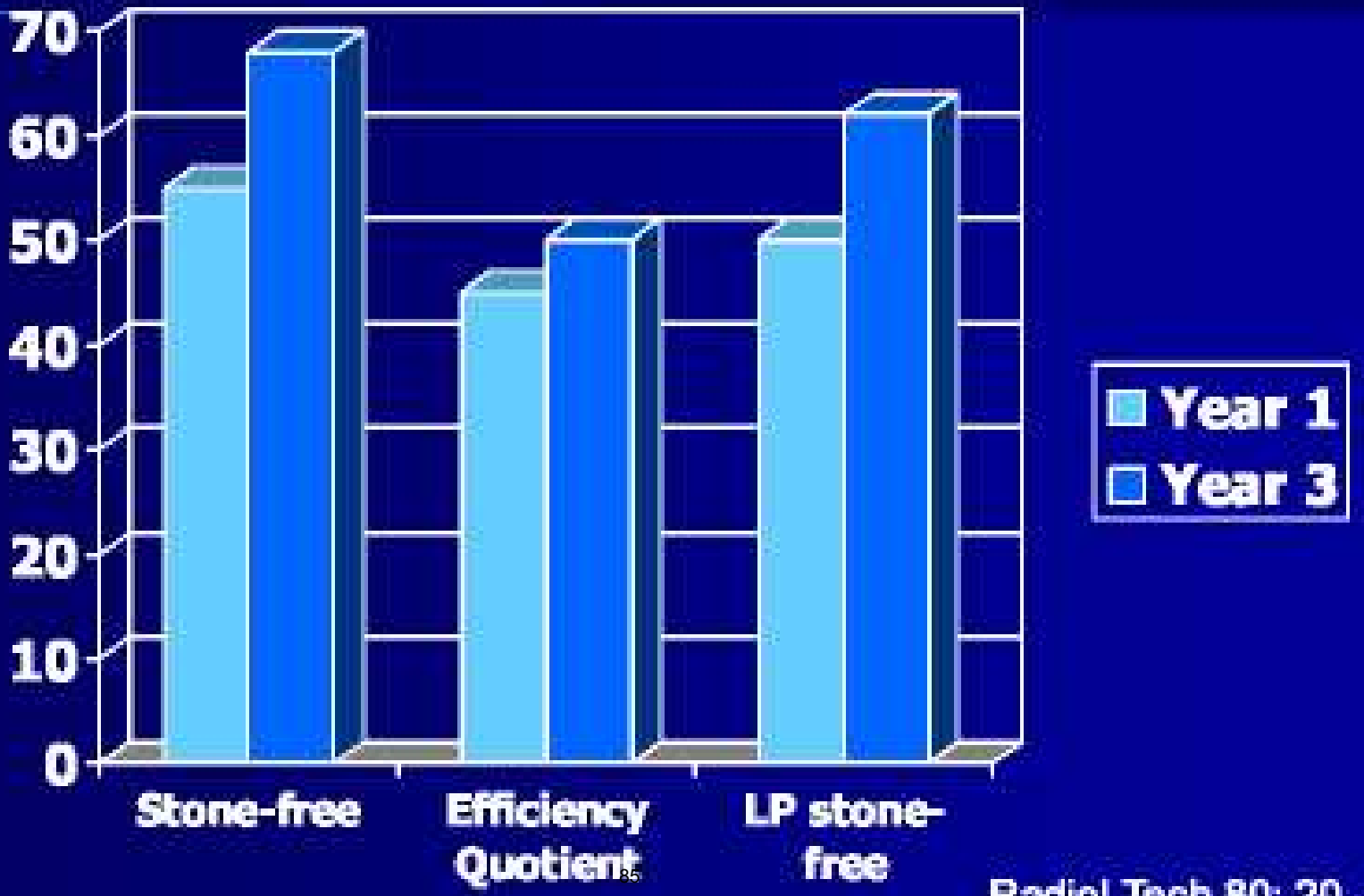


- 3 minute pause between priming shocks and treatment is the key

BJU Int. 2009 Jan;103(1):104-7.

Exhibit 7

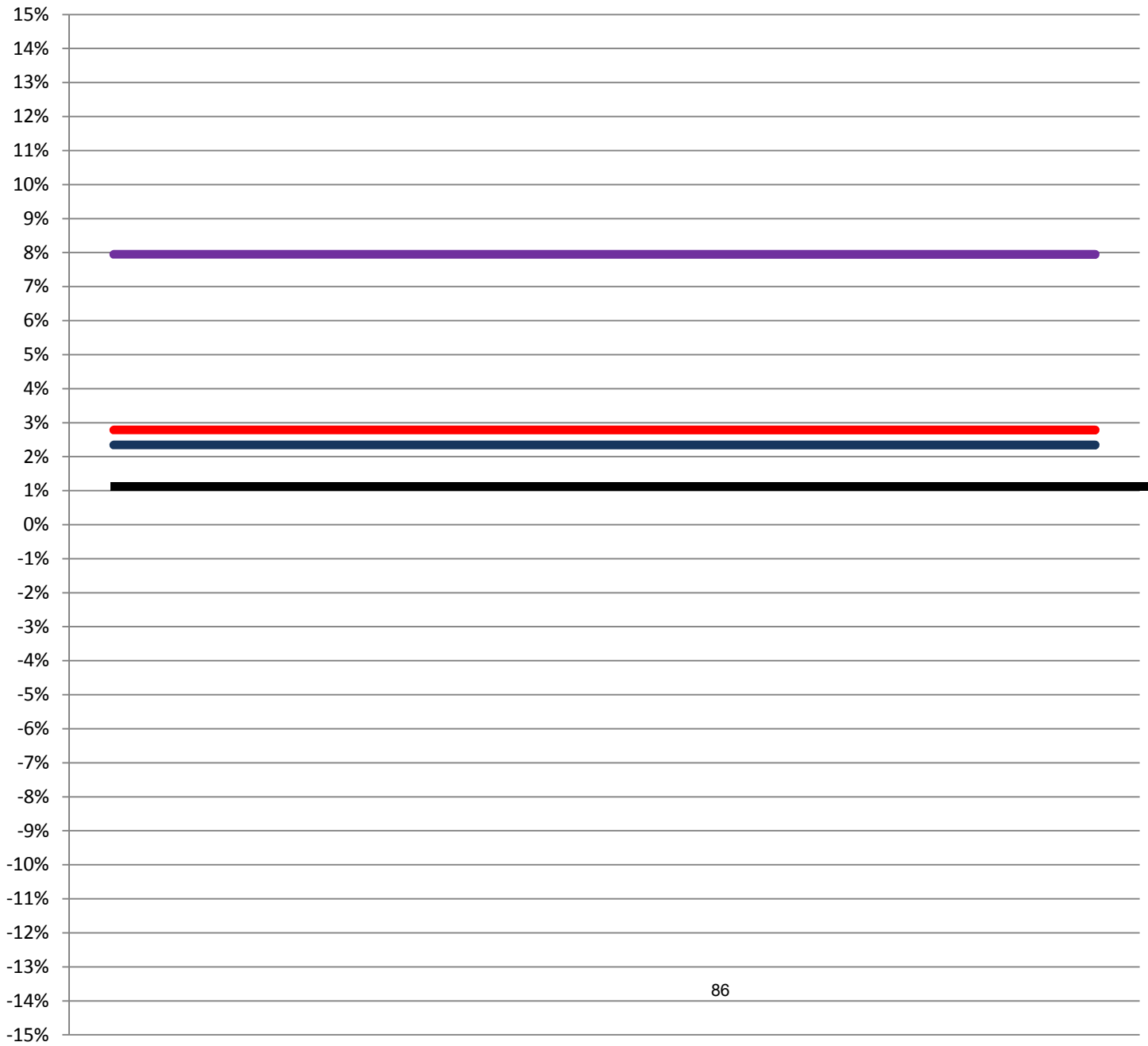
Litho Tech Learning curve



Radiol Tech 80: 20, 2008

Exhibit 8

Attachment G



Percentage Above Avg. National Contract Rate

Illinois +7.95%

Ohio +2.78%

Michigan +2.34%

AKSM Avg. National Contract Rate

Percentage Below Avg. National Contract Rate

UMS
UNITED MEDICAL SYSTEMS

July 17, 2013

Mr. Edward B. Goldman,
Chairman
CON Work Group, Lithotripsy

Re: CON Regulation for UESWL Services

Dear Mr. Goldman,

Thank you for the opportunity to participate in the Lithotripsy CON Workgroup last month. I thought the meeting was well attended and brought all of the key issues to the forefront for a very substantive discussion. As requested at the meeting, I am writing to follow up with documentation on some of the issues discussed.

As discussed last month, Michigan can be proud of having one of the most successfully implemented CON regulations, of any state. Quality, access and cost, are benefitting all the constituents who have an interest in providing this important service to the citizens of Michigan. Changing the regulation status of Lithotripsy can only have a negative impact on the three main objectives of the law.

Attached is a summary of the notable points discussed at last month's meeting, including references to attached documentation. We believe the continued regulation of lithotripsy under the CON standards is appropriate. We believe that health facilities, patients, and payers are all best served by the continued regulation of lithotripsy under the Certificate of Need program. I appreciate your time in chairing the workgroup and bringing these points to the CON Commission for their consideration. Please feel free to contact me directly with any questions at 1-800-516-9425.

Respectfully,

Jorgen Madsen
CEO

1500 West Park Drive, Suite 390
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682
www.ums-usa.com

Certificate Of Need

Mission: Access, Cost & Quality

Access:

Under the current lithotripsy CON structure, UMS and GLL have 7 mobile Units providing service at more than 65 sites of service. In 2012, the Units provided 1271 days of service, averaging 15 days of service per month per unit. Based upon an average of 21 business days per month, this leaves 6 days of service available on each Unit for a total of more than 500 days per year still unused. In addition, the average number of cases performed per day was 7 during 2012. Each Unit is capable of doing up to 14 or more cases per day. Any facility not currently receiving lithotripsy services can apply for a CON and generally be approved based upon current capacity levels. There should be no waiting lists at any facility. Any facility, whether large or small, urban or rural, can have lithotripsy service access if needed.

Cost:

Lithotripsy units cost anywhere from $600K to $800K depending on manufacturer and configuration. By mobilizing these units and spreading that cost over multiple facilities, the cost impact to the healthcare system is dramatically reduced. Nationally, the charge by a mobile lithotripsy provider to the facility receiving service is between $2,200 and $2,400 per procedure (see attached SEC 10K filing from HealthTronics). However, in Michigan the average rate is between $1,400 and $1,500 per procedure.

Quality:

Currently, our average technologist does more than 100 lithotripsy procedures per month, or more than 1,200 per year. The techs become highly skilled in the procedures because of this high level of volume. Quality comes from repetition (see attached American Urological Association White Paper). The average tenure of technologists in the GLL Michigan fleet is 9 years (see attached technologist experience data).

Deregulation consequences:

If deregulation were to occur there would be a massive proliferation of lithotripsy equipment within the State of Michigan. Each hospital or physician's practice of reasonable size would engage in a "technology arms race" to promote that they have the "next best widget" in lithotripsy. The need to recover the cost of this influx in technology will no doubt drive the pricing of services higher and could lead to unnecessary procedures being performed. In addition to the potential for higher costs, the quality of service would suffer as the technologists, who operate the Units on a day-to-day basis, would perform less procedures and the level of overall skill would degrade.

Access, quality and cost would potentially be negatively affected in particular for small and rural facilities after deregulation. Under the current system, facilities do not pay a different price due to their size and all receive the same high quality of service. If the higher volume accounts were cherry picked, either with own units or other possible scenarios, then the cost of servicing smaller and lower volume accounts would go up and unfairly disadvantage those smaller rural facilities.

Lithotripsy is not regulated under any law other than the CON. With deregulation there would be no limit to what setting could be used to facilitate the procedure. Lithotripsy is a relatively safe procedure, but only if provided in the right setting with proper medical back up capacity (see attached AUA White Paper). We do not believe that, for example, a physician's office would be the most appropriate setting for the procedure. However we have seen plenty of examples in non CON states, where the financial incentive drove a movement to perform the procedure in a less optimal setting.

An example of another urology procedure/device where the lack of CON regulation has resulted in undesirable consequences can be found in the so called DaVinci robotic procedure. Here is an example of how the "Medical Arms Race" has had a negative effect on all three of the major tenets of CON: cost quality and access. Due to competitive pressure from large urban medical facilities, many smaller hospitals have bought this technology, to ensure their competitiveness, even though it is not financially feasible as a standalone decision. Many times this can be driven by a need to attract physicians to these rural facilities. However, unless a physician performs a large number of these robotic procedures, his/her skill set is never going to be proficient. As a result, quality suffers, costs rise, and access to quality care is not benefitting. There are many law suits in progress around the country regarding the use of this technology and we encourage the commission to further investigate what the negative consequences to unfettered access can result in. (See attached CNBC article on the Da Vinci robot.)

Statements that are predictive in nature, that depend upon or refer to future events or conditions, or that include words such as "will", "would", "should", "plans", "likely", "expects", "anticipates", "intends", "believes", "estimates", "thinks", "may", and similar expressions, are forward-looking statements. The following important factors, in addition to those discussed under "Risk Factors" under Part I, Item 1, could affect the future results of the health care industry in general, and us in particular, and could cause those results to differ materially from those expressed in such forward-looking statements.

- uncertainties in our establishing or maintaining relationships with physicians and hospitals;
- the impact of current and future laws and governmental regulations;
- uncertainties inherent in third party payors' attempts to limit health care coverages and levels of reimbursement;
- the effects of competition and technological changes;
- the availability (or lack thereof) of acquisition or combination opportunities;
- the integration of acquired business; and
- general economic, market or business conditions.

General

We provide healthcare services and medical devices, primarily to the urology marketplace.

Lithotripsy services. We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2009, physicians who are affiliated with us used our lithotripters to perform approximately 50,000 procedures in the U.S. We do not render any medical services. Rather, the physicians do.

We have two types of contracts, retail and wholesale, that we enter into in providing our lithotripsy services. Retail contracts are contracts where we contract with the hospital and private insurance payors. Wholesale contracts are contracts where we contract only with the hospital. The two approaches functionally differ in that, under a retail contract, we generally bill for the entire non-physician fee for all patients other than governmental pay patients, for which the hospital bills the non-physician fee. Under a wholesale contract, the hospital generally bills for the entire non-physician fee for all patients. In both cases, the billing party contractually bears the costs associated with the billing service, including pre-certification, as well as non-collection. The non-billing party is generally entitled to its fees regardless of whether the billing party actually collects the non-physician fee. Accordingly, under the wholesale contracts where we are the non-billing party, the hospital generally receives a greater proportion of the total non-physician fee to compensate for its billing costs and collection risk. Conversely, under the retail contracts where we generally provide the billing services and bear the collection risk, we receive a greater portion of the total non-physician fee.

Although the non-physician fee under both retail and wholesale contracts varies widely based on geographical markets and the identity of the third party payor, we estimate that nationally, on average, our share of the non-physician fee was roughly $2,100, respectively, for both 2009 and 2008. At this time, we do not anticipate a material shift between our retail and wholesale arrangements, or a material change in our share of the non-physician fee.

WHITE PAPER

Current Perspective on Adverse Effects in Shock Wave Lithotripsy

TASK FORCE MEMBERS: JAMES E. LINGEMAN, M.D., CHAIR; JAMES A. MCATEER, PH.D.; DEAN G. ASSIMOS, M.D.; JOHN BAXLEY, PH.D.; ROBERT I. KAHN, M.D.; AMY KRAMBECK, M.D.; BRIAN R. MATLAGA, M.D.; DAVID PENSON, M.D.; GLENN M. PREMINGER, M.D.; PEI ZHONG, PH.D. **STAFF:** HEDDY HUBBARD, PH.D., MPH, RN, FAAN; EDITH BUDD; MICHAEL FOLMER; KATHERINE MOORE; KADIATU KEBE **CONSULTANTS:** KIRSTEN AQUINO; JUDY GOLDFARB; ANDREW P. EVAN, PH.D.
WRITING ASSISTANCE: DIANN GLICKMAN

INTRODUCTION

In May 2006, a peer-reviewed paper published in *The Journal of Urology* reported the findings of a long-term follow-up study at the Mayo Clinic in which it was concluded that patients treated by shock wave lithotripsy (SWL) had an increased incidence of diabetes mellitus and were more likely to develop new-onset hypertension.[1] This report drew immediate attention in the popular press and sparked editorial comment in the urology literature.[2,3] Although research dating back to the 1980s had established a link between SWL and hypertension in some patient groups, the Mayo Clinic report was the first to suggest diabetes mellitus as a potential long-term consequence of lithotripsy. At the present time, it is widely accepted among clinicians that SWL is a safe procedure, and that the complication rate and severity of adverse effects are minimal and tolerable considering the benefits of this entirely noninvasive therapy. However, it has long been recognized by researchers that shock waves (SWs) can cause injury to the kidney and that acute tissue damage due to SW treatment can be significant.[4-7] Now, with the possibility of chronic, life-altering adverse effects linked to lithotripsy, it is clear that the potential for long-term effects in SWL needs to be addressed.

As patient safety is a fundamental concern of the American Urological Association (AUA), a Task Force (Appendix 1) was established to provide expert opinion on the issue of adverse effects in SWL. The following report offers perspective on the current status of SWL with the goal of addressing three main questions 1) Is shock wave lithotripsy safe? , 2) Are the chronic adverse effects linked to SWL significant? , 3) Do the advantages of SWL outweigh the potential risks? This report focuses on clinical evidence. However, information from animal studies is reviewed to illustrate the tissue effects of shock wave energy.

CURRENT STATUS OF SHOCK WAVE LITHOTRIPSY

Shock wave lithotripsy was introduced as a clinical treatment for renal calculi by Chaussy and colleagues in Munich in 1980 utilizing a prototype device, the Dornier HM1 (for Human Machine).[8] The first widely distributed clinical lithotriptor, the Dornier HM3, was introduced to the United States in February 1984. This was followed by rapid acceptance of this noninvasive technology as a treatment alternative for renal and ureteral stones in the United States.

At the time of its introduction into clinical use, SWL was applied to a broad spectrum of upper urinary tract stone problems. With growing experience, urologists realized that there was a limit to the ability of the kidney and ureter to discharge stone fragments and, thus, the concept of stone burden (stone size and number) became important in selecting appropriate patients for lithotripsy. Currently, SWL is indicated for most uncomplicated upper urinary tract calculi; that is, an aggregate stone burden of <2 cm in kidneys with normal renal anatomy. Shock wave lithotripsy is also considered an appropriate alternative for the management of ureteral stones anywhere in the ureter with a few caveats (pregnancy, mid and lower ureteral stones in women of child bearing age).[9-11]

A number of factors can affect outcomes in SWL. For example, some mineral types (i.e., homogeneous cystine, brushite, some calcium oxalate monohydrate stones) are particularly resistant to fragmentation by SWs.[12] Renal anatomy can be problematic and in particular, stone location in the lower pole, the presence of renal anomalies (horseshoe kidney, calyceal diverticula, renal ectopy) and significant hydronephrosis all reduce SWL stone-free rates.[9] The effectiveness of lithotripsy is affected by body mass index, and studies indicate reduced outcomes when skin-to-stone distance is greater than about 10 cm.[14] In addition, outcomes for a given lithotriptor may be affected by factors such as the experience of the operator and the treatment protocol, but there is also evidence to suggest that some lithotriptors are less effective than others.[13, 15-19]

In summary, the advantages of SWL include its noninvasive nature, the fact that it is technically easy to treat most upper urinary tract calculi and that, at least acutely, it is a well tolerated, low morbidity treatment for the vast majority of patients. On the other hand the disadvantages of SWL are that retreatments may be necessary, and there appears to be a volume of fragments (when stone burden exceeds ~2 cm) that becomes problematic for the ureter to discharge.

LITHOTRIPSY ADVERSE EFFECTS

SHOCK WAVE LITHOTRIPSY TRAUMA TO THE KIDNEY: ACUTE EFFECTS AND MECHANISMS OF SHOCK WAVE INJURY

Animal studies have clearly established that SWs cause damage to the kidney vasculature.[4-6, 20] Morphological analysis of pig kidneys treated with a clinical dose of SWs has shown that veins are particularly susceptible to injury and that vascular damage occurs to a broad range of vessels, from vasa recta and cortical capillaries to intralobular and arcuate arteries and veins.[4, 6, 21, 22] Most animal research in SWL injury has been conducted using the Dornier HM3 electrohydraulic lithotriptor, but all lithotriptors studied have produced vascular damage.[23]

Shock wave lithotripsy can cause parenchymal bleeding and mild to severe subcapsular hematomas. Radiologic detection of hematomas in patients after SWL was perhaps the first indication of the adverse effects of SWs.[24] Although some hematomas persist, it is reported that most resolve without lasting adverse effect.[25] Large hematomas, while uncommon, are a potentially significant clinical event that may lead to blood transfusion and acute renal failure, fortunately rare events.[26-31] Hematoma rates may depend in part on the type of lithotriptor as values of less than 1% and up to 13% have been reported for different machines.[6, 32, 33] Understandably, detection of hematomas is higher when computed tomography or magnetic resonance imaging is used.[34, 35] Clearly, not all patients are equally at risk of developing hematomas. Increasing age has been identified as a risk factor for hematoma development. Excluding individuals with clotting abnormalities, it has been reported that the incidence of hematomas increases about two-fold per decade.[36]

Most of what is known about shock wave injury to the kidney comes from work with experimental animals where invasive methods can be used to assess for damage at the tissue level. The standard for assessment of SWL trauma to the kidney is quantification of hemorrhage in the parenchyma. Such bleeding within tissue cannot be observed by routine x-ray or CT and is not linked to the occurrence of hematomas. Thus, the absence of a hematoma by x-ray or CT does not rule out the occurrence of potentially significant trauma to the SWL-treated kidney.

Tissue damage in SWL is dose-dependent. Studies in experimental animals have demonstrated that lesion size (i.e., the volume of hemorrhagic tissue) increases with the SW number and with the power setting of the lithotriptor.[37-39]

The precise physical mechanisms responsible for tissue damage in SWL have yet to be determined. A variety of studies suggest that cavitation (bubble formation and collapse) is involved, but other mechanisms may be at play as well.[23, 40, 41] Evidence that cavitation is involved includes the observation of increased hemorrhage when micro-bubbles or gas-laden micro-beads are injected into the circulation during SWL.[42, 43] It has also been shown that strategies to suppress cavitation, such as using

tandem delayed SWs or a phase-reversed waveform to interrupt bubble growth, significantly reduce tissue damage.[44, 45] It is important to note that cavitation does not occur readily in circulating blood, and it can take hundreds of SWs to generate bubble activity within tissue in the living kidney.[43, 46] This suggests that cavitation may be highly dependent on the micro-environment of the vasculature. It is hypothesized that cavitation within blood vessels is dependent on the presence of minute particles that act as nuclei for cavitation bubble formation. It has yet to be determined what constitutes a natural cavitation nucleus in the circulation, but the fact that cavitation does not initiate readily suggests that the blood vascular system is relatively free of such particles.[43] Shock wave induced shear has the potential to damage tissue, and such a mechanism may contribute to injury, particularly at fast SW rates. In vitro experiments have shown that when isolated cells are held under static pressure greater than the threshold for cavitation, SWs cause more cell lysis than in untreated controls.[47] This suggests that cell injury occurs in the absence of cavitation. In an in vivo study, pigs were treated with SWs from a lithotriptor (Dornier HM3) fitted with a reflector insert that suppressed cavitation without significantly reducing SW amplitude. This dramatically reduced vascular injury compared to animals treated with the standard reflector, but these animals still showed a modest degree of bleeding involving vessels of the renal papillae.[45] A subsequent numerical modeling study suggests that stress can accumulate within kidney tissue if the SW rate is faster than the displacement relaxation time of the tissue.[48, 49] The model predicts that the magnitude of shear deformation of the renal parenchyma varies for different regions of the kidney, and the portion of the renal medulla (inner medulla) closest to the tip of the papilla, the area of the kidney that is most susceptible to SW injury, will undergo the greatest strain. This lends support to the idea that vessel rupture could be induced by shear and that subsequent bleeding could create an environment for cavitation, in turn creating further SW damage.

In summary, lithotriptor SWs can cause acute tissue injury, primarily damage to blood vessels. This hemorrhagic injury is dose-dependent and can be severe. Hematomas can occur as a consequence of SWL but do not serve as a reliable marker of SW injury. Cavitation is a likely mechanism for SW injury, but shear may be involved as well.

CHRONIC INJURY: THE POTENTIAL FOR LONG-TERM ADVERSE EFFECTS IN SWL

A critical issue, central to the theme of this report, is the question of whether SWL injury can lead to long-term adverse effects. The limited research that has been conducted in this area indicates that long-term effects do, indeed, occur as a result of SWL. Renal scar formation may develop after

SWL. This was demonstrated in patients using Single Photon Emission Computed Tomography (SPECT) to measure exclusion of Technicium-99 label from areas of poor vascular perfusion. [50] Patients scanned before and 30 days following SWL showed a loss of marker uptake, and scars that developed measured larger (mean 19x15 mm) than the focal zone of the lithotriptor that was used.

Studies with experimental animals also show that acute SW damage leads to scarring. Chronic damage of this sort was first reported in a laboratory study in which dogs treated with SWL showed fibrosis after one month, and the severity of scarring was dependent on the dose of SWs.[20] A study in rabbits, likewise, showed a dose-dependent increase in scar formation one month after treatment and a significant increase (nearly 10-fold higher) in scar volume with treatment at 2,000 SWs compared to 1,000 SWs. [51] The inner medulla of the kidney may be particularly susceptible to SW damage, and a study in juvenile pigs has shown that treatment with 2,000 SWs can lead to complete atrophy of the renal papilla at three months post-SWL.[9]

Although these manifestations of chronic injury have been identified, it seems likely that the full spectrum of long-term injury—the form and severity of chronic adverse effects—has yet to be determined. It is intuitive that chronic effects derive from acute tissue damage, but very little is known about the progression of tissue changes that link the two. There is also limited information about treatment dose and the development of chronic effects and whether specific risk factors exist that predispose an individual to long-term effects.

New-onset hypertension is a potential consequence of SWL, and evidence suggests that blood pressure changes following lithotripsy may be dose dependent.[6, 23] This topic has stimulated considerable debate, as not all findings agree, but the implications posed by reports showing a link between SWL and hypertension are cause for concern.[1, 52-59] A credible prospective study by Janetschek et al. showed an increase in intrarenal resistive index in patients 60 years of age and older.[52] This finding implies that SW treatment for stone disease can have serious, long-lasting effects, and that age could be a risk factor.[55] One can only speculate about what cellular level mechanisms might be at play; however, the observation that SWL can stimulate mesangial cell proliferation in pigs up to one month after treatment suggests a potential causative factor.[60]

A POTENTIAL LINK HAS BEEN IDENTIFIED BETWEEN SWL AND THE DEVELOPMENT OF DIABETES MELLITUS

The Mayo Clinic retrospective case-control study by Krambeck et al. evaluated the long-term effects of SWL on 630 patients with renal and proximal ureteral stones treated with SWL using the HM3 lithotriptor in 1985.[1] A survey was sent to those patients still living in 2004 (489 patients). Patients

were asked to report on new conditions that developed since their original SWL. Survey response rate was 58.9% (n=288). Responders were matched 1:1 with regards to age, gender, and year of presentation to a group of urolithiasis patients treated conservatively (i.e., no surgical intervention) who were continuing active follow-up.

The study found an increased risk of developing hypertension at long-term follow-up after SWL compared to the control group (Odds Ratio [OR] 1.47, 95% Confidence Interval [CI] 1.03 to 2.1, p=0.034). The development of hypertension was also associated with bilateral SWL treatments (p=0.033). An additional and potentially concerning finding was that patients treated with SWL were more likely to develop diabetes mellitus compared to controls at long-term follow-up (OR 3.23, 95% CI 1.73 to 6.02, p<0.001). This risk persisted in multivariate analysis controlling for presence of obesity in 2004 (OR 3.28, 95% CI 1.49 to 7.24, p=0.003) and change in body mass index over 19 years (OR 3.75, 95% CI 1.56 to 9.02, p=0.003). The development of diabetes mellitus in the SWL group was also associated with the number of shocks administered (p=0.005) and the total intensity of the treatment (p=0.007). A follow-up article from the same group noted stone recurrence in 154 (53.5%) of the 288 SWL patients treated in 1985 at 19 years follow-up.[61] Pre-existing diabetes mellitus was not associated with recurrent stone events (p=1.000); however, recurrent stone events were associated with the development of diabetes mellitus (p=0.020).

The authors noted limitations to the study and did not make causal claims; however, they offered possible explanation for their findings. Reference is made to prior reports of acute symptomatic pancreatitis after SWL, providing evidence that the pancreas can be affected by SWs.[62] In addition, there is reference to a study demonstrating elevated serum amylase, lipase and urinary amylase up to one week after SWL of proximal ureteral and renal stones, while these enzymes were not increased when lower ureteral stones were treated.[63]

The Mayo Clinic report stimulated commentary that has urged caution in interpreting the results, citing several methodologic biases in the study design.[2, 3] First, the control patients in the study represent a different patient population. Average stone size of the control group was 0.45 cm (0.1 to 2.0) compared to 1.08 (0.2 to 3.0) in the SWL group; thus, the control group is considered to have less severe stone disease than the SWL group. Differences in stone size were not controlled for in multivariate analysis. Second, family history, a known risk factor for the development of diabetes mellitus, was not reported for either cohort. Also, outcome data for patients treated with SWL were obtained through self-report while data for controls were collected through chart review, which has the potential to introduce collection bias. Although there was a good response rate to the questionnaire, it is possible that patients who experienced adverse events may have been more likely to respond than those who had not. In addition, it has been demonstrated that stone formers are already at increased risk of

developing diabetes mellitus and hypertension.[64, 65] Finally, the data from this manuscript reflects early SWL experience using a first-generation lithotriptor with a relatively wide focal zone and modest pressure amplitudes. It is uncertain as to whether these findings can be generalized to current practice using lithotriptors that have narrower focal zones. Without prospective randomized trials, studies on SWL are limited to retrospective reviews. However, when forced to work within the confines of a retrospective review, matched case-control comparisons can provide statistically sound data. In the Mayo Clinic study, the control group, although comprised of stone formers, had a different severity of disease compared to the SWL group. However, due to the accessibility and liberal use of SWL, it would be a difficult task to identify patients with symptomatic stones that have not undergone surgical interventions such as percutaneous nephrolithotomy or SWL. Ureterorenoscopy for symptomatic renal calculi may be used as a control group in the future, but not until ureterorenoscopy for renal calculi is widely available and used for 20 years can the same matched comparison be accomplished.

Two recent retrospective studies conducted after publication of the Mayo Clinic report have found no association between SWL and the development of diabetes mellitus. [66, 67] However, limitations in the experimental design of these studies leaves the question of potential for development of diabetes mellitus following SWL unanswered. [68] That is, in the study by Makhlouf and colleagues the duration of the follow-up period was only 6 years—likely too short a period to be relevant to the development of chronic disease. In the report by Sato and co-authors, follow-up was long-term (10-22 years, average 17 years) but the treatment dose was much lower (~900 SW) than is typically utilized around the world. As it is well established that tissue injury in SWL is dose-dependent the report of Sato and colleagues is unfortunately not particularly reassuring.

Until further studies of comparable design become available, the Mayo Clinic paper should be viewed as a warning of possible long-term adverse consequences of SWL, prompting further clinical and basic science translational research.

In summary, there is some evidence to suggest that long-term adverse effects of several types can develop as a consequence of SWL. Animal studies in particular suggest that the acute hemorrhagic lesion progresses to scar formation, resulting in loss of functional renal volume. Renal subcapsular hematomas can be long lasting but the medical consequences of this are unknown. A prospective study indicates that elderly patients are at increased risk of developing new-onset hypertension following SWL. In addition, a 19-year follow-up study has found an association between SWL and the onset of diabetes mellitus and hypertension.

TREATMENT STRATEGIES WITH THE POTENTIAL TO IMPROVE SWL

Recent studies show that changes in procedure and technique can improve SWL outcomes. Such advances include reduced tissue injury when the protocol includes a brief pause following the initiation of treatment, and both improved stone breakage and a reduction in injury when SWL is carried out at slow SW-rate.

PRETREATMENT PROTOCOLS HAVE THE POTENTIAL TO PROTECT AGAINST SWL INJURY

Studies in the pig model have demonstrated that treatment with a priming dose of low amplitude SWs reduces renal injury in SWL.69 Delivery of a dose of 2000 SWs with the Dornier HM3 lithotriptor using settings typical of clinical treatment (24 kV, 120 SW per minute) created a lesion measuring approximately 6% of functional renal volume (FRV). However, initiating treatment with as few as 100 low power SWs (12 kV) before completion of the dose with the higher amplitude pulses resulted in a significant reduction in the size of the lesion to 0.3% FRV. Recent research suggests that the power level of the priming dose is not the factor responsible for this protective effect, as the lesion volume was similar when the priming dose was delivered at 12, 18 or 24 kV.70 Instead, it was observed that inclusion of a three to four minute pause following the priming dose was protective, while increasing the power setting without this delay did not result in reduced injury. That is, injury was reduced only when the priming dose was followed by a brief delay. These findings are potentially important as they suggest a simple treatment strategy to reduce adverse effects in SWL.71 Such treatment protocols need to be confirmed in a clinical setting.

SLOWING THE SW FIRING RATE REDUCES RENAL INJURY AND IMPROVES STONE BREAKAGE OUTCOMES

Recent studies in pigs shows that slowing the firing rate of the lithotriptor to 60 SW per minute or slower reduces lesion size in the kidney to less that 0.1% FRV compared to ~6% FRV at 120 SW per minute.[72, 73] That is, slowing the SW rate results in protection against renal trauma similar to that observed using the low SW power pretreatment or pause-protection protocols.[69, 70] Such results from animal studies are encouraging, but similar studies have yet to be conducted with patients.

Stone breakage is affected by SW rate, and a number of clinical studies report that slowing the firing rate of the lithotriptor to 60 SW per minute gives better outcomes than treatment at the typical rate of 120 SW per minute.[74-79] This effect is seen with both electrohydraulic and electromagnetic lithotriptors. The advantage of slowing the SW rate is that fewer SWs are needed for treatment, but a potential disadvantage is a modest increase in overall treatment time.

CONCLUSIONS

We return to the main questions posed at the outset of this report.

IS SWL SAFE?

Since its introduction into the US in 1984, SWL has been performed with great success on millions of patients, but not unlike a surgical procedure, SWL carries the risk of unintended consequences. Shock waves have the potential to cause tissue damage and acute injury may lead to long-term adverse effects. There is likely a treatment threshold for initiation of SWL injury, but the upper limit for SW dose that can be delivered without causing vascular trauma is not known. It is highly likely that the vast majority of patients who are treated with a typical dose of SWs using currently accepted treatment settings experience some degree of acute renal trauma. It is not known if such injury sustained from a single treatment session alone leads to lasting damage. Animal experimentation demonstrates the severity of acute SWL injury. Whether or not acute SW damage progresses to long-term effects likely depends on SW dose (i.e., not only SW number but power, SW rate, and treatment sequence), as well as pathophysiologic risk factors that predispose the patient and/or kidney to a heightened response or particular pattern of response. The risk factors for acute SWL injury may not be the same as those for chronic effects. Thus, the safety of SWL depends on multiple factors that include the dose, treatment settings and acoustic characteristics of the lithotriptor used, frequency of retreatment, and a background of physiologic factors that may predispose the patient to increased risk of acute injury or progression to long-term damage. Recent studies with experimental animals demonstrating that renal injury is significantly reduced at slow SW rate or when a protective "pretreatment" protocol is used are very encouraging, and suggest that under proper conditions lithotripsy can be both safe and effective.

ARE THE CHRONIC ADVERSE EFFECTS LINKED TO SWL SIGNIFICANT?

Research to date suggests that SWL may lead to potentially significant chronic adverse effects including new-onset hypertension and diabetes mellitus. The long-term consequences of acute SW injury deserve further investigation.

DO THE ADVANTAGES OF SWL OUTWEIGH THE POTENTIAL RISKS?

Shock wave lithotripsy is often the best treatment option, in some settings may be the only treatment available and in most cases presents distinct advantages that outweigh the foreseeable risks. Like any of the stone technologies there are risks in using SWs, but it is also true that new treatment strategies are being developed that reduce adverse effects and improve stone breakage outcomes. Steps that

significantly reduce acute injury may have the potential to eliminate long-term adverse effects altogether. Still, limited understanding of the factors that lead to lasting injury after SWL calls for continued research on the mechanisms and consequences of SW injury.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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Michigan Lithotripsy Technologist Experience
United Medical Systems/Great Lakes Lithotripsy

	Start Date with UMS/GLL	UMS Years of Service	Prior Service	Years of Service
Litho Tech #1	1/27/1999	14.4	0.0	14.4
Litho Tech #2	6/18/2003	10.0	0.0	10.0
Litho Tech #3	2/1/2005	8.4	10.0	18.4
Litho Tech #4	12/16/2005	7.5	5.0	12.5
Litho Tech #5	4/1/2006	7.3	6.0	13.3
Litho Tech #6	1/8/2007	6.5	0.0	6.5
Litho Tech #7	6/24/2013	0.0	7.5	7.5
	Average	7.7	4.1	11.8

CNBC.com

Robotic Surgery: Growing Sales, but Growing Concerns

BUSINESS FRAUD, COMPANY MISTAKES, BUSINESS NEWS, CNBC, INVESTIGATIONS INC, HEALTH CARE EQUIPMENT, INVESTIGATIONS INC., INTUITIVE SURGICAL INC, FDA, BUSINESS NEWS

CNBC.com | Tuesday, 19 Mar 2013 | 11:04 AM ET

When Intuitive Surgical went public 13 years ago at $9, it dazzled Wall Street with its sizzling story of something that would revolutionize medicine: a surgical robot called the da Vinci.

Born in Silicon Valley, the da Vinci was steeped in technology so advanced that it "overcomes many of the shortcomings" of traditional open surgery, notably less blood loss and a faster recovery, Intuitive boasted in its IPO filing.

Since then, da Vinci hospital robot placements and procedures have skyrocketed. Last year alone, installations rose by 21 percent to 2,585 units worldwide at a cost of more than $1.5 million each. And robotic surgical procedures leaped by 25 percent to 450,000.

While one of the downsides of robotic surgery is a lack of tactile feel, surgeons who sit at a console a few feet from the patients raved about its 3-D vision. "The vision compensated for everything," world-renowned prostate specialist Dr. Ash Tewari of New York Presbyterian Hospital said in a recent interview. He performs as many as four of the two-to-three hour procedures a day, four times a week. "If you look at it from a surgical standpoint, every surgeon's dream is to get to see exactly what he or she is doing and get to do it in a field (of vision) which is not pooled with a lot of blood."

Such testimonials have helped propel Intuitive into what Northland Capital analyst Suraj Kalia calls "the 'Apple' of the medtech sector."

Intuitive, which builds and sells the machines, also collects more than $100,000 in service maintenance agreements for each machine and sells the disposable instruments used by the machines for surgical procedures.

With revenue last year topping $2 billion, its stock has climbed well above $500, propelling its current market valuation to more than $20 billion.

In recent years, as the da Vinci's popularity has grown, so have questions and concerns about its safety, training and the aggressiveness of its marketing.

Intuitive executives declined to be interviewed for this story, and a spokeswoman said the company would not comment on issues of safety, training and marketing because they are "within the context of active litigation."

However, at a recent investment conference, Intuitive dismissed safety concerns, telling analysts that given the number of procedures it does, it believes its safety record is "exemplary."

And in a statement to CNBC, Intuitive said: "In any definitive treatment for complex disease, such as surgery of the cancerous prostate, heart, or other major organs there are risks of complications. Robotic surgery has proven benefits in reducing the risk and complications associated with open surgical procedures thereby extending the benefits of minimally invasive surgery to a broader population of patients. Overall, adverse event rates are very low. Da Vinci surgery has been shown to be safer than the open surgery alternatives in numerous independent large scale, peer reviewed studies."

Many surgeons, including critics, agree that in the right hands the da Vinci is generally safe.

However, a CNBC Investigations Inc. review, which included numerous interviews with surgeons,

lawyers, ex-employees and patients and an extensive review of internal documents, multiple studies, lawsuits and depositions of current employees, shows:

- A sharp rise in lawsuits and complaints about injuries, complications and even deaths following da Vinci procedures. At least 10 have been filed over the past two years, most of them in 2012; many more complaints, plaintiffs attorneys says, are headed toward mediation.
- Surgeons can use the robot to operate on patients after several steps, including at least an hour of online training, four hours watching two full-length procedures online, seven hours operating on a pig and as few as two surgeries, overseen by a more seasoned robotic surgeon. The number of supervised cases can vary by hospital.
- A high-pressure sales culture driven by quarterly "quotas" on surgical procedures has led sales people to lean on surgeons to do more robotic surgeries, according to interviews with former salespeople and internal emails.

On its website, Intuitive promotes the da Vinci as superior to open surgery, with such benefits as less blood loss, faster recovery and less pain.

In some procedures, such as hysterectomies, robotic surgery is being promoted and used as an alternative to laparoscopic surgery, another so-called "minimally invasive" surgical technique. A recent study published in the Journal of the American Medical Association concluded that "To date, robotically assisted hysterectomy has not been show to be more effective than laparoscopy."

And in prostatectomies, while robotic surgery is likely to result in less blood loss and faster recovery than traditional open surgery, the most feared side-effects of all—incontinence and sexual impotence —"are high after both," according to a study released last year by the Journal of Clinical Oncology.

Just last week, in what amounted to a stinging rebuke of robotic surgery, the president of the American Congress of Gynecologists and Obstetricians said: "Many women today are hearing about the claimed advantages of robotic surgery for hysterectomy, thanks to widespread marketing and advertising. Robotic surgery is not the only or the best minimally invasive approach for hysterectomy. Nor is it the most cost-efficient. It is important to separate the marketing hype from the reality when considering the best surgical approach for hysterectomies."

(*Read More:* Gynecologists Urge Caution on Robotic Hysterectomies)

The Food and Drug Administration recently asked surgeons to take part in a voluntary survey asking about complications involving the da Vinci. The FDA told CNBC the surveys are a routine part of its surveillance to help evaluate the device and its performance and to help understand the risk/benefit profile for devices like this.

Injury Complaints

"The robot has a place in surgery," said Dr. Francois Blaudeau, a practicing Alabama gynecologist who also is lead plaintiffs attorney focused on da Vinci-related injuries. Blaudeau, who has been trained on the da Vinci, also cautions that "it is a sophisticated piece of equipment that has its own set of issues." One, he said, is that it can inadvertently cause serious injury.

According to lawsuits, complaints, interviews with alleged victims, plaintiff attorneys and an FDA's database, many of the reported injuries during robotic surgery appear to be burns and other heat-related damage to intestines, ureter, bowels and other organs. Blaudeau and several surgeons interviewed for this story said the injuries can occur beyond the surgeon's range of vision and without the surgeon's knowledge and may only show days after the surgery. This, plaintiff lawyers say, has meant that many of the injuries and complications in the complaints have not been reported to the Food & Drug Administration as a da Vinci issue, resulting in an under-reporting of "adverse events" related to the machine.

Instead patients, unaware of a possible link between robotic surgery and their injuries, have in the past filed malpractice suits against doctors and hospitals, Blauedeau said. Intuitive declined to comment on the specific number of lawsuits and complaints. "Patients and attorneys have a right to make legal claims," a spokeswoman said. "We take any claim seriously, evaluate it on its own merits and trust in

the legal system to resolve these matters."

(**Read More:** What Happens When a Surgical Robot Malfunctions?)

The best official source for medical device "adverse events" is the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Submissions are voluntary, based only on reported cases and have not necessarily been investigated by the FDA. In fact, the agency cautions that it "is not intended to be used to evaluate" rates of adverse events. And doing so, Intuitive said, would be "factually and contextually inaccurate."

Since 2000, the database shows reports of at least 85 deaths and 245 da Vinci-related injuries. (A complete spreadhseet of 4,600 adverse events, including machine malfunction, filed with the FDA is included in this Intuitive report by Citron Research, which does investment research.)

During the same period, roughly 1.5 million robotic procedures have been performed, suggesting reported problems are statistically insignificant.

But critics like Dr. Marty Makary of Johns Hopkins University Hospital believe the number of injuries and complications are under-reported. A study he co-authored, which is under review by the Journal for Healthcare Quality, cross-referenced the FDA's database with press reports and lawsuits and found eight cases that were either incorrectly or never filed with the FDA.

While that may be a "fraction of procedures that are done," said Makary, the industry has done "a poor job of monitoring the safety profile of certain new technologies, and this is a classic example."

Makary, a pancreatic specialist known for doing complicated procedures—and trained on the robot—prefers straight non-robotic laparoscopy because of its lack "of what we call haptic (tactile) feedback. Because we're working around blood vessels, an inadvertent injury could result in a catastrophic bleed in seconds."

Yet, he added, "we have not even been keeping a national registry of robotic surgery-related complications. And from the ones that we have, we know from our research there is a massive under-reporting."

Blaudeau said after last fall's launch of his website badrobotsurgery.com—and in the wake of several lawsuits he filed—he has received "hundreds" of what he says are "confirmed" complaints involving "ureteral" and other injuries" during da Vinci gynecologic procedures.

And in the three months since advertising robotic injuries for Blaudeau's law firm on television in local markets, "We've probably had over 10,000 calls regarding vascular injuries, bowel, bladder, re-surgical procedures, punctures and tears," said Loni Liss, president of the Legal Communications Group, which conducts advertising campaigns seeking plaintiffs for personal injury lawsuits. "That's a very large response."

Among those who responded was Sonya Melton of Birmingham. Following six weeks in the hospital after what was supposed to be same-day robotic surgery, she said, she was home recovering and watching TV when "I see one of these commercials for attorneys. And they're talking about anyone had any problems with a robotic surgery. I'm like, 'hmmm.' … I start to do a little bit more research. And I was like, 'Well, is that the name of the robot that they used on me? Yeah, it is.'"

In an interview, she said she had become so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die. Her condition, she said, puzzled doctors so much that within days they sliced open her stomach open to find out why she was in excruciating pain and had developed a full-fledged pneumonia. What they found, she said, was a perforation in her small intestine.

Shawn Todd, who lives outside of Mobile, Ala., also contacted Blaudeau's firm. She still breaks down and sobs when she tells how doctors, unable to get anesthesia to work, apologized for what they were about to do as they held her down and stuck needles into her kidneys, which had shut down. Turns out, she said they told her, her ureters, which carry urine from the kidneys to the bladder, had somehow been burned.

Intuitive declined to discuss both cases, which are in mediation.

Blaudeau and other surgeons we spoke with say they believe one reason for the injuries is the da Vinci's use of "monopolar" energy for cauterizing and cutting, which can create excessive heat. If there is a failure in insulation on the instruments, they said, it can cause what is known as a "stray current" or arching—when sparks from an instrument leap elsewhere.

Stray currents can occur in regular laparoscopy as well. However, a 2011 study published in the American Journal of Obstetrics & Gynecology said, "robotic instruments have a significantly higher incidence and prevalence of [insulation failure] compared with laparoscopic instruments."

Intuitive said instruments using monopolar energy have been employed in "open and laparoscopic surgery for decades," and the company is "confident that the da Vinci surgical system deploys monopolar energy in a safe and effective way when used as indicated."

The company said it offers instruments that use various types of energy, and "surgeons determine which energy instruments to use."

Training on a Pig

Surgeons, plaintiffs lawyers and at least one lawsuit cite training as a concern. Typically it involves seven hours of training over a weekend, usually operating on a pig.

Then, based on the hospital's criteria, the surgeon is required to conduct two to five surgeries supervised or "proctored" by an experienced robotic surgeon before doing their first unsupervised operation. The more practice, in general, the better, but that also adds to the cost of training.

"Many surgeons are trained the same way, with no differences made as to their prior knowledge or prior ability prior to entering the robotic training," Bladeau said. "It's not reasonable to believe that every surgeon across the country can be adequately trained with one pig lab and two proctored cases."

It was a lack of training, according to one lawsuit filed in Washington state, that ultimately led to the death of Fred Taylor in 2012, roughly four years after undergoing what was supposed to be a routine prostate surgery.

His was the third robotic case for Dr. Scott Bildsten—his first without a supervisor. Instead of taking a few hours, the lawsuit alleges, the surgery lasted around 13 hours and 26 minutes. Two hours later, Taylor was "intubated in an ambulance" after suffering from a torn rectum, losing 15 cups of blood and undergoing "a consequent hypovolemic shock," a lawsuit filed by Taylor's widow claims.

"The weeks and months to come showed the results of the surgery were devastating," it states. Taylor never fully recovered. The lawsuit alleges he died of complications from the surgery.

Meanwhile, Bildsten, according to his deposition in connection with the lawsuit, "gave up robotics forever" one year after he operated on Taylor, saying:

I was under the initial impression you would get a level of comfort within a certain number of cases. And as .... it went along, it seemed it was going to be much longer than that. ... And after speaking with some other urologists in a similar situation, who attempted to use the ....da Vinci robot prostatectomy, a lot of others have decided not to proceed as well. They found the learning curve so steep and lengthy that the level of comfort just took too long and decided to quit. I was one of those.

Neither Bildsten nor his lawyer returned calls seeking comment. Intuitive, in keeping with its policy, declined comment on the lawsuit.

The Marketing Drive

Underlying all of this, according to former salespeople and internal emails, is a company culture steeped in aggressive marketing techniques, that includes high-pressure sales efforts by Intuitive to hospitals and doctors.

"Our extensive field checks highlighted a story where aggressive marketing drives the message and

true clinical utility seems secondary in nature," wrote Kalia, the Northland Capital analyst.

Intuitive declined comment on Kalia's report.

His comments are supported by our interviews with former Intuitive salespeople and internal documents, including those filed with the Taylor lawsuit. One common theme is an effort to prod surgeons to "convert" previously scheduled non-robotic surgeries to robotic surgeries to meet quarterly sales quotas.

In one email, Intuitive's clinical sales director bemoaned how the "Mountain West team is forecasting about 285 procedures each week. We need to be at 345 procedures/week to close on our goal."

With two days left in one quarter, another sales leader wrote: "Let's bring it home! Be sure to scrub all schedules, identify cases on Thursday and Friday that can be moved up. ... Turn over every stone possible. I know there are 2 out there."

In another email that day, another sales leader wrote: "Guys, it's time to call in favors for these last 2 cases. ... We need to start calling our surgical champions who know our business first thing tomorrow."

Other emails show sales reps trying to persuade hospitals to lower the amount of supervised surgeries required before surgeons can operate solo.

Marketing the robots to the hospitals, the former salespeople said, was just as aggressive. "We would go to hospitals in a local geography and get docs to pledge they would take business away to other hospitals if their hospital didn't get the robot," said one former regional sales director, repeating something several sales reps said.

With Intuitive, the marketing is to doctors, hospitals and something quite unusual for a surgical device: marketing directly to the consumer.

Hospitals proudly display banners and advertise the arrival of the da Vinci. Northwest Medical Center in Margate, Fla, even put up the da Vinci outdoor billboard with slogans like "The Power Performer" and "da Vinci, same name, same genius."

Some hospitals that have the robot, however, have kept it low key. Massachusetts General, for example, has one robot, has never actively promoted it and has capped the doctors who can use it. "We have had a very conservative, cautious and skeptical approach to the use of it," said anesthesiologist Dr. Peter Dunn, who also oversees the hospital's new surgical technology as head of its perioperative operations.

Dunn said that after five years, Mass General, which prides itself on being on the cutting edge of new medical technologies, has determined the robot has not proven to be the best solution for all patients.

And while the hospital continues to consider new uses for the robot, Dunn said, "more important than the device, is the quality of the surgeon."

URL: http://www.cnbc.com/100564517

Lithotripsy Literature Search from HFHS

A literature search identified several complications that can arise with lithotripsy procedures:

Complications

- Perforation of the upper ureter
    - Case study: ureteral perforation can cause a series of problems including the retroperitoneal urinoma, urosepsis, abscess formation, infection, and subsequent renal function impairment. (1)
- Large subcapsular hepatic hematoma
    - Case study: severe hemaorrhagic shock required a partial coiling embolisation of the right hepatic artery. (2)
    - Large hematomas, while uncommon, are a potentially significant clinical event that may lead to blood transfusion and acute renal failure (3).
- Acute pancreatitis, perirenal hematoma, urosepsis, venous thrombosis, biliary obstruction, bowel perforation, lung injury, rupture of an aortic aneurysm and intracranial hemorrhage
    - Case study: Acute necrotizing pancreatitis (4)
- Intrarenal hematomas, interstitial edema, and temporary tubular dysfunction
    - Case study: reversible acute tubular necrosis in a nonobstructed system (22)

Although these complications occur in a small percentage of cases, they can still be life threatening. It is important that lithotripsy is provided in the appropriate setting in order for patients to be monitored in an environment where services are available to address any complications that may arise.

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Prepared by: Megan Passman, Student, Planning June 2013

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June 13, 2013

c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street
Lansing, Michigan 48913

Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for continued dedication to proffer decisions that ensure access to affordable, quality health care for residents of Michigan. I hereby submit this letter as formal testimony on behalf of my mother, a Michigan resident who is unable to represent herself but would if she could. My testimony is intended for your sincere consideration during this time while you and your workgroup consider 2013 Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

UESWL is an *EFFECTIVE* means for treating kidney stones. UESWL, however, is <u>not</u> a *SAFE* means for treating kidney stones. Shockingly, no pun intended, safety has not been proven. The term *SAFE* cannot simply be used interchangeably with the term *EFFECTIVE*. In 1984, under extremely heavy pressure by American urologists to approve UESWL technology in the United States, the FDA abdicated. It could easily be seen that UESWL worked; kidney stones could be "pulverized" as they claimed. But it was also demonstrated that ESWL could just as easily destroy lungs, spleens, the pancreas, kidneys, normal heart rhythms, etc. To this day, nearly thirty years later, without good faith research the FDA had entrusted to the urology community, the *SAFETY* of UESWL remains no more than a matter of wishful thinking.

The *FACTS* heretofore concerning UESWL safety have proven highly inconvenient for economic interests of American urologists; simultaneously in 1984, a plan was hatched and UESWL became a booming "service business" for urologists to make a lot of extra money. A lot of extra money. Urologists assumed the conflicting duality of roles as both physicians to patients and producers to shareholders. Creating this vehicle for so much extra money is based entirely on inflating contract prices with healthcare facilities and increasing patient volumes treated with UESWL services in which non-provider urologists have so-called "ownership" shareholder interest. The more patients treated with UESWL, the more money these syndicated urologists ("shareholders") make. It must be a volume-based business; just ask the "*Council for Urological Interests."* Wink, wink, nudge, nudge. A UESWL "service" syndicate typically consists of merely providing a lithotripter, technologist, truck, and driver under contract to healthcare facilities.

Research shows that after thirty years we still don't know which patients should be treated with UESWL and who shouldn't. It is entirely possible that hundreds of thousands of patients who've been treated with UESWL may have been far more safely served by alternative treatments. But a lot of extra money stands directly in the path for any adequate medical research to measure grave safety hazards of this technology and establishing any properly vetted patient selection process. It is highly offensive and mocks patients' distinct rights to in any way sanitize the brand of sheer plunder that is urologist-syndicated lithotripsy "service." The neglect for proper research to be conducted when safety has not been proven over three decades has had dual effects: (1) It creates an operating environment in which safety somehow became a dangerously false assumption, and (2) it robs patients the freedom with which to make highly consequential medical choices based on factual science, I might add whilst they are often in agonizing pain.

Today we are publically witnessing that standard mainstream economic theory construes all our motivations, whatever their character or source, to be "preferences" and assumes they are additive. However, this blindly misses the distinctly corrosive and even fraudulent effects of money, Honey. Patients cannot "prefer" UESWL based on cost or quality when they are not offered clear, truthful, and objective information concerning safety, cost, or alternatives. And quality standards can in fact be trusted only when clear, truthful, and objective information is achieved and communicated to the public.

The effect on the characteristics of a product or activity such as mobile UESWL service in this case, by allowing it to be evaluated exclusively or predominantly on commercial terms rather than by scientific, medical, altruistic obligation, is a grave and serious matter. Make no mistake; the commercialization process wrought with the self-serving economic reasoning that propels it alters the "product," and the soundness of medical reasoning for mobile UESWL service. There should be no sort of accepted common assumption that a hyper-inflated commercialization process does not affect an outcome or product such as UESWL on moral and medical terms. This would flagrantly insult the public's intelligence.

When we blindly permit market reasoning to replace tangible evidence of medical harm, we are placing our bets on the economic provision that a "free market" will simply act as it does and ultimately correct itself. Really? How on earth will the "free market" ever correct itself when sick and vulnerable patients receiving this market-tainted UESWL procedure are not provided even the slightest opportunity to know hard, critical facts about the harmful nature of this procedure? How will the "free market" ever correct itself if market-based reasoning prevents better treatment methods from being be used and/or newly developed? How will the "free market" ever correct itself when patients are not actually choosing any properly offered objective alternatives based on honest facts? How many thousands of people will be harmed while the urology community willfully conceals and callously ignores the inopportune fact and disturbing evidence that UESWL is not safe in favor of a lot of extra money? How many decades must pass?

At what measurable human cost will we permit them to continue fulfilling their argument for market reasoning? How many patients will "walk in" with a kidney stone, and "walk out" with diabetes, hypertension, a splenectomy, or renal failure instead? How will market reasoning deal with such mortal, moral implications, when patients may believe they are making therapeutic decisions with their urologists in good faith based on confirmed safety measures, when they may actually instead be unwittingly making significant life-altering, or life-and-death decisions due to critical facts undisclosed to them?

Adverse effects of UESWL have essentially never been voluntarily reported to the FDA. Therefore, safety oversight is effectively nonexistent for a procedure that still has not been proven safe! Is this what we mean by "freedom?" Achieving a thirty-year hiatus for responsibility to measure and report safety of UESWL has been accomplished by means that have been tribal, predatory, organized, and highly secretive in American urology. Billions of consumer healthcare dollars have by now been taken and used against the consumer in order protect the "freedom" of this outrageous under-the-radar plunder by these urologists and their market-forward "business managers."

Research shows that UESWL predisposes patients to diabetes, among other serious life-threatening conditions. Based on what was known about the trauma of this procedure and the "blast" path of the shockwave treatment, this is and was predictable. Diabetes is the leading cause of kidney failure, lower limb amputations, and new cases of adult blindness. It is a major cause of heart disease and stroke. Medical expenses for people are more than double for patients with diabetes than for those without diabetes. 67% of people with diabetes have concomitant hypertension. 60-70% of diabetics suffer nerve damage. Diabetics are more susceptible to life-threatening infections. Diabetes cuts of 8.5 more years of life off the average 50-year old with diabetes than the average 50-year old without diabetes. Diabetes costs the U.S. an estimated $174 Billion per year. Urologists are neither tracking nor reporting patients for such adverse effects. So, do kidney stone patients "prefer" UESWL and the risk for diabetes they otherwise may never suffer? Maybe we should ask them. Maybe we should be solving the diabetes epidemic rather than causing it.

If for example, a drug were prescribed for morning sickness that clearly proved to remedy morning sickness, but caused horrible teratogenic defects in women's fetuses, would that drug be considered safe? Or effective? If a drug were prescribed to readily remedy gastrointestinal ulcers, but also caused major bones to break ten years down the road, would that drug be considered safe? Or effective? Was Fen Phen safe? Or effective? If lithotripsy were performed to readily "pulverize" kidney stones, but caused diabetes, hypertension, renal failure, ruptured spleen, damaged pancreas, loss of functional renal volume, and death would that procedure be safe? Or effective? Is it even legal to withhold the facts of grave risk from a patient when the FDA has never proven safety of the procedure? It is not okay for it to be this way for UESWL and as

humans we know this. What is most disturbing is that the urologists also know this. It is their principal responsibility to know this.

Risk cannot be offset when the facts are carefully concealed by a cloistered one-sided market-based argument, especially over thirty years. Rather than working in a deliberate, concerted effort to devise treatment methods that CAN be determined to be safe, instead we have gotten every excuse in the book for deploying UESWL. Neglecting and hiding the medical facts about UESWL in favor of its commodification is morally outrageous, repugnant, and grotesque. UESWL has become the "moneyball" of medicine, at unfathomable cost to healthcare consumers kept in the dark.

After nearly thirty years of gravely consequent inattention to the medicine of UESWL in favor of its role in the marketplace, this has all gone desperately way too far. UESWL is a very easy "sell" to the patient population at large. It is "non-invasive," a term effectively bandied about to convey that which diminishes risk of harm. It is nearly as simple as that. Who would endure the risk of an "invasive" surgical procedure, when a kidney stone could effectively be "pulverized" and passed "non-invasively?" What a perfect tag line, "non-invasive."

But what patient would actually risk consenting to a "non-invasive" procedure if he knew the alternative "invasive" procedure would protect him against diabetes, hypertension, renal failure, and many other life-altering, harmful and deadly medical effects of UESWL? Patients are not choosing, because patients are not given the facts; their rights to choose have been severely abused. In the "let the buyer beware" marketplace, this might be okay, but in medicine for the sick and vulnerable it is not remotely okay, and the two should never be permitted to be confused. Any urologist's argument for UESWL "being the best technology we have now" is immaterial in absence of proper disclosure to patients for the dire risks posed by this procedure. It is a non-argument, because it is purely anecdotal.

Market-based reasoning does not concern itself with the medical facts when they conflict and you can otherwise hide them; no need for medical reasoning when the market-based argument is humming along nicely and no one is watching. We have seen this in other cases. Urologist "shareholders" in the massive national UESWL organized "Outfit" as here in Michigan, would in fact be acting against "shareholder" economic interest were they to subvert their roles as their company's producers in favor of applying judicious, scientific medical reasoning; wouldn't that breach their "shareholder" responsibilities? It would! Market based reasoning is concerned almost exclusively with how you manage to convincingly "sell" the "product," the medical facts be damned for the sake of improving "profitability." Besides, the thirty year absence of accountability in medical research permits them to claim just about anything at this point.

So the real question is this: What will it be: The market, or honest medicine? That this could even be such a conundrum demonstrates just how debased we have become. There

should never be any question or conflict between the full faith of honest medicine and the subversion of truth for corrupted market-based callous indifference. This is a matter of basic human decency, why we educate ourselves, and it is what separates us from the eat-or-be-eaten wild.

If the FDA were charged only with granting approval for effective technologies, we would be living in a very different world today. But it is their distinct obligation to the American people that technologies are both effective ***and safe***. We, as voting citizens in a democracy have chosen efficacy *AND* safety. But again, in 1984 the FDA abdicated; practically speaking those authorities may even be dead by now, it has been so long ago. They passed their authority for learning the safety of UESWL over to the medical community of urologists in good faith, believing practicing urologists would report concerns and/or confirmations about safety risk back to them; they expected them to do the research. They didn't do it. After nearly thirty years, any trust the FDA might have had in urologists to competently and honestly raise vital concerns or lack thereof about UESWL safety has been badly violated. It is time to measure the cost of this serious breach of trust.

Simply taking money away from some and giving it to others doesn't cut it. Somewhere in the exchange, value must be established and met with a critical eye. So, what is the value of UESWL? If it does not include safety, just how valuable is this procedure? If it costs billions just to treat adverse effects of the procedure, just how valuable is this procedure? And who now is deciding on what merits the basis for value of UESWL is founded? Somewhere therein lies the core of its provision under principles of cost, quality, and access.

Were there to be no payments made until the proper research is completed to discern safety of UESWL, what do you predict might happen? Would medicine be the prevailing force for patient care, or would it remain based on the corrupted market forces in this case? Would a truly effective *AND* safe technology for kidney stones suddenly emerge in the marketplace? Somebody needs to call it; the jig is up and we must act.

We urge you to act in your utmost capacity and authority to decide that quality care must include clear provisions of *SAFETY* and *EFFICACY;* that access to UESWL become far more judicious, and that patient consent forms for CON approved service sites be submitted to MDCH CON for approval. UESWL is a procedure that has not been proven safe and should be very carefully monitored for harmful costs in both life and treasure. We urge you to consider advising MDCH to develop a public service program for kidney stone prevention in Michigan. We urge you to seek out talented Michigan engineers and scientists to find safe and effective technologic solutions for kidney stone removal; we must fix this diabolical problem.

Please help to find some other legitimate way to pay urologists to be clearly objective in their work; this whole disgraceful UESWL scheme must end. Please measure your

response to deploying UESWL delivery standards in the context of cost, quality, and access based on the facts, and not merely on market-based wishful thinking.

Thank you for your dedicated service.

Sincerely,

Anne Mitchell
US Citizen
Ae_mitchell@comcast.net

Cc: The Public

August 22, 2013

Via email

Michigan Department of Community Health
CON Commissioners
Certificate of Need Policy Section
c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
201 Townsend Street
Lansing, Michigan 48913

Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for your dedicated commitment for cost effective access to quality healthcare in Michigan. This written testimony is intended as public comment for your September 17, 2013 meeting and for consideration during your analysis and discussion of UESWL standards in this critically important review period.

Kindly, first consider the money alone; $100,000,000.00. No joke, this is pretty beefy; it is a very conservative estimate over the past eight years for the amount Michigan healthcare consumers alone have paid ***in excess of direct costs*** for mobile lithotripters and UESWL technologists, regardless of CON oversight for cost, quality, and access to UESWL. In the United States over the past thirty years of urologist-syndicated UESWL "service," comparable excessive overpayment can easily be estimated at over $11,000,000,000.00.

Health Systems, urologists, syndicators, and insurance carriers have full knowledge of the excessive overpayment metrics of this outrageous scam; certainly we can all perform simple math. Patients, healthcare consumers, the people who paid this money, though, don't have a clue. Why are we allowing this heist? Really, why? Surely there is a clear, transparent explanation for this monumental thievery, so kindly oblige the people of Michigan with the tale, the truth, and the real story. We all deserve to hear a manner of valid explanation for this "free-for-all" spree that even we plebs can understand. Please explain the value and benefit we have received for the outrageous amount of money we've overpaid and day after day continue to spend on a traumatic procedure ***not proven to be safe***; it is time we are given the answers. What did healthcare consumers receive in concrete terms for their money? Where did this money go?

What if we'd spent this $100,000,000 on actual medical care instead of on kickbacks? Please give distinct consideration to the fact that these were real people's healthcare dollars; it is reasonable to expect they will actually be spent on healthcare, to cure disease, to improve health, and not spent on a frivolous roll of the dice played with people's lives so that the Outfit can succeed to realize the heist of the century. This is very, very serious.

In the past month, our NIH Director, Dr. Francis Collins, a man with substantial ties to Michigan, has allocated $96,000,000 for "Big Knowledge Data Centers;" this is one reasonable example for how $100,000,000 healthcare dollars could be spent. This recent NIH allocation is constructive by contrast, and perhaps Michigan could seek a little redemption and a piece of this prize. With its strong history and infrastructure already in place, MDCH and the CON Department could actually provide the kind of high quality data our nation desperately needs to clear a pathway for

combatting a national epidemic of costly, deadly kidney disease, for example; to actually help people.

How about it? Step forward! It could be a collaborative effort with arguably our country's finest institution for population research; the University of Michigan. Ya'll are right here in our midst. You could get organized to do this critically important work in healthcare that our nation's urologists refuse to do but that our country sorely needs. If we could just get to some honesty about how all this kidney disease is destroying so many lives at such astronomical cost, some clear answers, maybe medicine can begin to properly serve the sick again. And ya'll might actually be able to help stop the burning of money on B.S. What's more, perhaps then a far more transparent and honest means of getting urologists paid for their work might emerge.

If not me, who? Somebody needs to just get really indignant out here about the unbridled greed and the dishonest, malicious deception of urology syndicated UESWL. Decorum is just too insubstantial, and does not rise to meet the outrageousness of this national UESWL debacle. How, otherwise will we ever meet our distinct responsibilities to move critically important medicine forward? It is long time to get out of this lax, blinding, haze of a cover up for "this is how we do things," of "this is how we were trained," and of "how can we most effectively game the system and 'find a better way'?" My blistering rant here is an attempt to deliver an opposing equivalent response by measure against the in-your-face, outrageous, deceptive, malicious, shameful, deadly exploitation of the Outfit's UESWL scheme. This has gone way too far down a deadly road now, with the compass having been tossed out the window long ago, and we simply must reestablish proper moral and scientific navigation. It is the decent, human thing to do. It is time to start over on a much more honest and trustworthy path.

I can easily think of at least a hundred far, far more constructive ways of spending $100,000,000 consumer healthcare dollars on actual health and medical care. In my finger-wagging tirade, I'll be happy to list them at your request, and they will meet rigorous cost/quality/access measures. Real measureable progress in reducing healthcare spending must include fair and reasonable oversight and cooperation; far, far more than merely letting the so-called "free market" exploiters their freedom to "compete" for just burning up all our healthcare dollars often on extremely grotesque, dishonest, and irresponsible schemes like these UESWL syndicates while nobody watches with a critical eye or cares about anyone but themselves. Oversight is needed if only to simply keep them domesticated.

It is time to focus; the money spent and the medicine delivered in no way or form should be separated. So, follow the money; it is clearly the law of our land. When it appears too good to be true, just follow the money and you will undoubtedly find bad medicine attempting to hide underneath. Take IMRT for prostate cancer; it is also there. Nearly seventy percent of radiation-treated prostate cancers are failures. Why should we permit Medicare to pay $40,000 or more/treatment for such colossal failure? When 7 of 10 fail? Really? So that the Outfit's salvage prostate cryotherapy procedures can then back these radiation failures up later on at even more outrageous cost? The metrics of these strategic IMRT schemes, when the math is done, are even more outrageous than the UESWL scams. What on earth? It is blasphemous and grotesque, especially considering the additional adverse effects of IMRT, like burning holes in the rectums of old (and young) men; especially when there is more and more evidence that it may be entirely possible to prevent prostate cancer in the first place! Nothing like having a colostomy to go along with all that radiation in your golden years!

Honest and critically informed oversight is needed to stop burning our scarce healthcare dollars so that medicine can actually be incented to move forward and improve! It is always a good idea when something doesn't pass the "sniff" test, if your first gut reaction tends toward "this stinks," to remember this is cause enough to challenge assumptions of what appears superficially to be an entirely offensive, stinking-to-high-heaven practice – because below the ground it probably is!

Consider the outrageous size alone of the sophisticated bait and switch cover-up of UESWL's unproven safety in favor of the scheming Urology Outfit's pure economic interest. You must admit, it is impressive. Barely below the surface, their highly organized and ***distinctly proud effort*** funded entirely by extracting ordinary people's healthcare dollars that were intended to pay for "facility fees," and their unchecked power to level what turns out to be serious life and death consequences in the absence of adequate risk disclosure, totally eclipses their interest in or responsibility for the actual medicine of UESWL. No one is responsibly examining the vast amount of money spent on adverse consequences of UESWL; a deep, black, cause-and-effect hole borne of arrogance and hubris. It is hard to estimate the billions of healthcare dollars flushed down that deep, dark hole, and the hundreds of thousands of lives cast tragically into serious chronic disease or the looming threat thereof due to this deceptive scheme. The money has been placed entirely in front of the medicine, because placing the medical facts in front of the money would simply poison and kill the money tree! UESWL is not safe; proof of safety is anecdotal at best. Outing the harm of UESWL would be just too much of a nationwide buzz-kill at this point.

You must ask: Do healthcare consumers consent to this? Is this what they want? Is this what they need? Do kidney stone patients know that urologists are intentionally playing roulette in the shadows with their kidney function, pancreas/ diabetes, spleen, etc., for the money? Hardly! Never ever forget that the basic tenet of medicine at its root is morality, and that it is consent that should inform and guide every moral and therefore medical decision. Consent: Honest and complete disclosure. Consent for what precisely will be delivered at what cost, with clear, fair, honest, responsible, competent warning both for adverse effects and financial implications.

We have just been standing by and watching this? Blindly trusting and permitting the teaming up of doctors, lawyers, hospitals, businesses, legislators, governments and more in a sophisticated and ungodly scheme to deny science and medicine in a planned, deliberate, and calculated effort to extort consumers' healthcare dollars from the system? It is malicious, duplicitous exploitation. Not only is it incredibly disrespectful, but grotesquely shameful. I would argue it is distinctly criminal. It borders on reigning terror. It is time for the public to understand the truth.

There are no properly vetted guidelines for treating or retreating, for example, a 1.0 mm kidney stone versus a 5.0 mm stone – so no one is actually tracking anything about the safety, difference in outcomes, or adverse effects of one versus the other! No one is held to any relevant account of the facts. Actually, none of this is being tracked at all, regardless of the stone size, trauma and the evidence! The decision to perform UESWL is entirely between "a patient and their doctor." Nice, because that is really pretty damn convenient for the Outfit. As long as the urologist can convince the patient behind closed doors, then the sky's the limit, practically anything goes, and the Outfit continues to control and call the shots! After thirty years, no one yet is asking questions?! While the renal transplant lists just grow longer and longer and longer? The test-strip business is booming and that of *metformin* and *metroprolol*. "Business" is booming! And the $Billions just keep being pumped over to the UESWL masterminds. Each passing year the Outfit

turfs a little more grease to legislators to make sure the skids stay slippery. UESWL in the United States provides a simple primer in how to keep Joe Six-Pack in his place. Poor and useful Joe Six-Pack: blindfold him, take his money, his tax dollars, his health, and then poverty-stricken, make him suffer until he dies.

Here are merely three of the questions concerning patient safety that an urologist should be required to fully and honestly answer following treatment of any patient with UESWL:

- Do you know whether you have fully or partially destroyed the functionality of the treated kidney?

- Do you know whether you have damaged the patient's pancreas or to what extent the pancreas has been damaged during UESWL?

- Have you fully disclosed to the patient what it means to fully or partially destroy the functionality of his kidney or damage his pancreas in terms of the future of his life, health quality, and finances?

The answer to these three questions will be "no" if the urologist has answered honestly. Instead, we hear, "Oh, but for our highly trained technologists with "X" years of experience!" The Outfit's canned "trained technologist" answer has nothing to do with answering these highly critical questions about safety. It is not enough that a technologist merely knows how not to kill the patient on the table as a measure of safety, or attempt to minimize damage. What needs to be known is the **truth** of the damage that has happened during a treatment. **Urologists do not know, nor is there evidence they want to know**. Because they are mostly controlled by the Outfit. If the urologist does not know the truth and is honest instead about not knowing, these patients should be given full understanding of the consequences and provide their truly informed consent concerning life and treasure for this complete crap shoot. Which begs the real questions: Where are the ***real*** statistics? Why are we allowing this? Are the alternatives much safer by comparison overall? Why on earth after thirty years don't we know?

Consent for the Outfit would look something like, "*Though I will make best efforts given the circumstances, today you are consenting to a procedure which may destroy or badly damage your kidney or pancreas. Other damage may also happen to your spleen, lung, arteries, etc., etc. Or you could die. Do you know what this means? If you live, it is entirely possible for the rest of your life that your medical expenses will be doubled, tripled, quadrupled, or more, and you may suffer a significantly poorer quality of life. Not knowing facts about UESWL likely costs the healthcare system hundreds of billions of dollars. UESWL is effective for breaking kidney stones. It also can badly damage or destroy vital organs, we just don't know, because the safety of UESWL even after thirty years of utilization in the United States has not been adequately researched on purpose. It is important to me, more than knowing the actual safety statistics of UESWL for you, that I have found a better way to make an extra $1500.00 or so more than my professional fee today by treating you with UESWL rather than alternative methods."*

I challenge any one of you to find one healthcare consumer or kidney stone patient who with full knowledge would consent to this UESWL heist on moral, medical, and financial terms given the facts. But the Outfit wants us to believe the facts are inconsequential, so they strive to hide them as anecdotes. Don't you think proving UESWL is what they say it is would be their obvious road

to redemption? So why doesn't the Outfit do it? With the millions they otherwise pay lobbyists, perhaps? Nothing valuable or actionable is in the medical literature on purpose. Nothing. Imagine the serious quality issues in all the variable and uncontrolled environments; have UESWL technologists ever once seen the physical harm they've caused a treated kidney or pancreas? Does one urologist out there have any knowledge whatsoever if he's caused damage enough to any one patient's pancreas via UESWL to cause their diabetes? **No** is the answer.

These adverse effects are not merely intriguing, fascinating, interesting anecdotes up for endless decades of discussion in the medical literature. They are about real people's lives! Why aren't the questions being asked? Shouldn't we require these answers in every case? What about hypertension caused by UESWL? It is entirely possible that for any given treatment, the functionality of the treated kidney may be entirely destroyed and the patient would never have any way of knowing… until it crept up later, insidiously. Isn't it a distinct ethical obligation to forewarn all patients of the research urologists have refused to do for thirty years prior to consenting to UESWL? What on earth are they doing? And why are we letting them get away with it? If cause and effect of UESWL is never defined, we're toast. A patient was killed outright in Michigan with UESWL; no one ever reported it to the FDA.

Critical knowledge of the history and facts concerning UESWL has been deliberately ignored by the Outfit, and in Michigan perhaps due in small part to the complacency coming from nearly thirty long years (yawn) performing the procedure under CON. You've been sold a bill of goods and your eyes have been taken off the ball. You've been turned by the oldest, slickest marketing trick in the book; that is, you've been made to focus on the money and not on the product. It takes minimal skill by salesmen to draw attention away from the product itself in order to focus you entirely on the exchange of money instead. They have magically created value where there is none. If you do not see what the product is actually doing, then it appears on the surface to be six of one, half a dozen of another. Marketing, enterprise, but this is **not medicine**.

Safety of UESWL is unproven. Period. Think; just how has it happened for healthcare consumers to have paid out an extra $11,000,000,000.00 dollars in this country and $100,000,000.00 in Michigan to urologist-owned syndicates for a procedure that has not been proven safe? Do you think it might just be the tap-dancing-we-have-trained-technologists, money-grubbing "market" incentive that ensures UESWL will never become proven by the data to be unsafe? It is time to get to the bottom of this by putting eyes back *on* the ball. Just who else is getting greased by this abusive scheme? You will find out if you will only follow the money.

Healthcare consumers deserve the performance bar to be raised here to at least a reasonable trustworthy standard, but this will require more participation from informed overseers, not less. CON especially today is critically important to healthcare, so long as money is not blindly separated from the medicine; it can be a tremendously effective means for vastly diminishing massive waste and fraud. In the case of UESWL it will mean saving people's lives. I cannot think of a more important time in medicine for there to be a pro-active, constructive CON Department with far more critical authority to focus on cost and quality by clearly analyzing clinical data. Recently, it was shown, for example, that one(1) PET scan performed at the right time is as predictive as five(5) PET scans performed in a prescribed follow-up period, though more research is needed. Without public oversight, the same kinds of incentives remain today that will keep healthcare costs in an uncontrolled spiral, regardless of ACO's. Nothing could be more important now than a reinvigorated, hearty, discriminating CON process and rigorous,

formative healthcare debate. Nothing could be more important now than connecting the money to the medicine. Public health systems need some real rocket fuel to bring us out of the harmful, wasteful financial mess that has been so prevalent in healthcare delivery for far too long.

If a procedure or process doesn't work, why should healthcare consumers pay for it? Why? What's it worth? Even more so, if it causes grave harm, why should healthcare consumers pay? Highly measurable cost savings depend on connecting real dollars to the actual medical value of any given diagnosis or treatment. Imagine, for instance, what happens *outside* a CON process when even within a CON process a quick and easy $100,000,000 and sacred medical trust for safe care can so easily be heisted from the public.

Now to the dirty little secret in medicine: ***Statistical Significance.*** Those of you here like me with research backgrounds completely understand the clarion call of statistical significance. Every medical doctor has implicit and thorough understanding of the importance of statistical significance; and when you do, you also easily recognize when it is obvious that intentional absence of necessary research represents dodging of a bullet. It is ***the*** bullet. It proves. It disproves. And when sidelined, absence of statistical significance permits absolutely nothing to be demonstrated, creating a convenient "Limbo-land." Limbo-land is the cowardly place to hide when you clearly, obviously find a problem you don't want to solve with an answer. It is the filthiest secret in medical research, holds us back, and disregarded for UESWL over thirty years while brazenly mocking patient safety, absence of statistical significance in favor of anecdotal tidbits concerning grave safety hazards has permitted billions of dollars to be siphoned over to the Outfit's urologist-syndicated "joint ventures." Limbo-land can kill people. For the money, one could hide in Limbo-land forever. It has given a level of power to urologists to sideline and neglect their distinct responsibilities to do no harm now for decades. How clever, and how evil.

The Outfit's carefully crafted magic sleight of hand has created a cheesy, shifty optical illusion in plain sight. Power consolidated out of the money they've heisted has fostered the kind of blinding haze for us to have trusted them and stood idly by for decades, while their defensive legal teams first constructed, then successfully lobbied, defended and upheld the deceptive UESWL joint venture "structures" for them. Using our healthcare dollars, this tactic was successfully deployed to divert attention away from the obvious, frightening truth behind the medicine being practiced within these "joint ventures." Highly organized, politically engaged, very well-greased urologists have been given carte blanche over thirty years to deploy UESWL without proof, disclosure, clear patient safety or critical follow-up guidelines. They've used the patients' heisted healthcare dollars to pay for policies to support and protect the heist. The cost to the public in life and treasure, to the "tax payer" of this is unimaginably massive.

Healthcare dollars not actually spent on the care intended by consumers spending the money has instead purchased urologists' ability to hide this dangerous standard of care behind a black curtain of anecdotes, and intentional, frightening neglect. Fully aware of the distinct problems, urologists have had complete power and great reason to take UESWL technology seriously, respect its failings, to conduct the straightforward work to prove its safety in patients, or to simply engage the FDA. But they've refused in obvious attempt to protect their own personal financial interests. Clear evidence of the nature of grave harm from this extremely poorly researched standard of care, entirely devoid of proof from an even remotely statistically significant body of research for safety over more than a generation, is long overdue and must be addressed now. Not knowing is dishonest and far too harmful. After nearly thirty years, time is up; enough is enough.

When obvious harm being done cannot routinely or obviously be predicted because the knowledge base is kept hidden, unknown, and protected within a well-funded national secret society of urologists, and where no appropriate follow-up testing is required in clear consideration of the potential for serious harm, government must step in to protect the public. There can be only one motivation for heinous, deliberate neglect to achieve evidence of statistical significance in the face of an obvious need to establish safety of this procedure after thirty years; MONEY. It is outrageous and deeply shameful. A few pretty pictures of pathologic kidneys do not tell any story whatsoever, so don't bother. Just follow the money and you will find the Outfit.

With cunning and sophistication, and a spin machine funded by money that was otherwise intended to have been spent on healthcare, the Outfit has permitted urologists, without financial risk, to conspire for nearly thirty years within their own trumped up consent decree and prosper in cooperatives by trafficking UESWL in a game of human rendition as if it were merely an element of some business balance sheet from a hedge fund. The Outfit's hedge fund where urologists perform the business functions, pull all the strings, and behave as combinations of CEO, CFO, risk officer, and medical practitioner, while betting their futures against the futures of their patient's lives. A hedge fund where they will continually win because of a merger with government officials that permits them never to disclose the significance of the danger they pose to hundreds of thousands of unassuming lives in order to keep the $$Billions flowing in and out. Follow the money; where it is coming from and where it is going. Then ask if human life matters.

When we trade truth, science, and medicine in favor of gamesmanship, politics, jockeying, lobbying, marketing, stealth and pure extortion, we lose any credibility whatsoever as standard bearers of science and medicine, or law for that matter. This has happened; we are here now and all the evidence and facts bear it out. Being a standard bearer first requires having standards in the first place. We are far better and smarter than this. In the words of President George Washington, "Let us raise a standard to which the wise and honest can repair…" We, here, together are responsible for permitting an outrage such as UESWL syndication to happen and it is long time to restore honesty and trust. It is time to reconcile accounts. It is time to require proof. It is time to stop burning the money. We cannot afford nor should we ever tolerate amoral treachery in medicine. This is not okay. It is long overdue to do the right thing by asking the right questions and taking action.

Here is a snippet for your pure entertainment of how the sick Outfit spins it in the case of *Endocare (Healthtronics)*, for example. Regardless of which faction, *AKSM, UMS, UST, Council on Urological Interests, Endo*, or whomever within the *Outfit*, it is textbook execution of the scheme. *Healthtronics* describe themselves in this way, *"HealthTronics was conceived over 25 years ago by a group of urologists looking for a better way. They discovered that partnerships and specialization helped everyone run a thriving, successful practice. While we have grown and added services, our focus has not changed, we have remained a company committed to the urology community."* Sounds like a harmless sound bite on the surface, "*looking for a better way*." Read between the lines – they found a better way, alright; but, certainly not by practicing medicine. Instead it was by plundering billions of healthcare dollars that had been designated to be spent on actual medical care, and by disrespecting untold numbers of lives. *"A better way."*

You've seen the *"AKSM Urology PAC."* Now meet the *"Endo PAC,"* draped oh-so-beautifully in the Stars and Stripes as a beacon of their "freedom," and see just how it is that the American

people, their hard earned healthcare dollars, and their freedom have been taken, hook, line, kidneys and pancreas as bait:

http://www.endo.com/File%20Library/About%20Us/Endo-2012-Annual-PAC-Contributions-Report_041813.pdf

You'll find Michigan's own Fred Upton on Page 7 of this juicy report. In 2012, the good Congressman Upton was fed his portion of the blood money by *Endo PAC*, while fulfilling his duty as others have described; "Upton has been recognized by Grover Norquist's Americans for Tax Reform as a "Hero of the Taxpayer" and by the U.S. Chamber of Commerce with the "Spirit of Enterprise" award." You betcha. And he's "pro-life" to boot! Sure.

In 2012, Endo paid a total of approximately $3.86 million for direct lobbying, approximately $2.21 million of which was at the federal level and approximately $1.65 million of which was at the state level. Endo paid a total of approximately $417,000 in indirect lobbying expenses in 2012. *Let me reiterate: these were consumers' healthcare dollars that were otherwise designated to have been spent on healthcare*. Do you think it mattered to the good Mr. Upton that he was paid consumer healthcare dollars sucked out of the system that were meant to have been spent on healthcare, and that he received this to keep the Outfit in the business of plundering American kidney function? Does Mr. Upton really care one way or another as long as his coffers are filled? Perhaps the good Congressman Upton will take action to support outsourcing of the creation of all this renal failure to Mexico as well! Perhaps we should designate Upton instead as "Hero of American Kidney Failure." Unfortunately for Joe Six-Pack, Congressman Upton is not the only one. Maybe we just need a new "Joe Six-*PAC* to counter with *anti*-blood money."

According to Endo, "There's always going to be a better way." Yep, we have that to look forward to: "*At Endo Health Solutions, we operate under a common set of guiding principles that enable us to provide quality products that serve unmet patient needs. Those principles allow us to focus on solutions for everyone in the healthcare continuum. Physicians want better solutions. Patients want to get better. Payers want a reliable financial model. Endo's collaborative, customer-driven approach enables employees to see a need, craft a solution and find a better way to guide our customers*." Read between the lines. Connect the terrorizing dots. Just imagine what they are capable of figuring out next.

This is a very serious life and death matter. Please exercise your authority by taking broad and factual understanding of UESWL and all its contrasting bounty and measly anecdote into account, and enact standards for UESWL delivery with proper perspective concerning patient health, safety, disclosure, and cost. Those who can do something must. I urge you to raise the bar and help us, and not to feed the beast as party to this human disaster.

Thank you for your dedicated service to Michigan healthcare, and for withstanding yet another of my very indignant but deeply sincere pleadings.

Sincerely,

Anne Mitchell
Ae_mitchell@comcast.net

Certificate of Need

Plans to Convert CON Standards to ICD 10

Beth Nagel, CON Policy
Tulika Bhattacharya, CON Evaluation

Attachment J

Conversion to ICD 10

Overview & Current Timeline for all of MDCH

- What is it?
  - ICD 10 is the 10th revision of the International Classification of Diseases used for morbidity and mortality reporting
- Who will it impact?
  - Converting to ICD 10 will impact all individuals, systems and procedures that create, record, update, process or report health care data based on medical diagnosis or procedure = Everyone!
- Why is it happening?
  - ICD 9 is limited in space and has obsolete terminology. ICD 10 allows for greater specificity, greater expansion and contains updated terminology
- When is it happening?
  - October 1, 2014

CON Conversion to ICD 10

Impacted Standards & Processes

- Five CON Review Standards are impacted (least to most complex)
  - Hospital Beds
  - Cardiac Catheterization
  - Urinary Extracorporeal Shock Wave Lithotripsy Services/Units
  - Positron Emission Tomography
  - Open Heart Surgery Services
- CON Annual Survey

Example: Hospital Bed Standard

- Hospital Beds section 4(1)(a)

(a) All Hospital discharges for normal newborn (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319 as principle diagnosis) will be excluded.

Example: Hospital Bed Standard

- Hospital Beds section 4(1)(a) – REVISED

(a) All Hospital discharges for normal newborn (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, see Appendix E for ICD 10-CM codes, as principle diagnosis) will be excluded.

Appendix E:

APPENDIX E

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

290 THROUGH 319	PSYCHIATRIC PATIENTS	F01.50-F99	MENTAL, BEHAVIORAL, AND NEURODEVELOPMENTAL DISORDERS

"ICD-9-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE **INTERNATIONAL CLASSIFICATION OF DISEASES - 9TH REVISION - CLINICAL MODIFICATION,** PREPARED BY THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES FOR THE U.S. NATIONAL CENTER FOR HEALTH STATISTICS.

"ICD-10-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 10TH REVISION - CLINICAL MODIFICATION, NATIONAL CENTER FOR HEALTH STATISTICS.

CON Conversion to ICD 10

Process Overview

1. MDCH Subject Matter Experts have provided a translation from ICD 9 to 10 for references in our standards
2. MDCH has validated the translation with statewide partners
3. Each of the five standards will be updated to include a translation chart as an appendix (keeping ICD 9 references in the language as a temporary transitional aide)
4. CON Commission will take proposed action on the 5 standards at the December 2013 meeting.
5. There will be a public hearing for the 5 standards
6. CON Commission will take final action on the 5 standards at the March 2014 meeting.
7. Standards will become effective in the May/June 2014 timeline
8. The regular schedule of Standards review will **NOT** be impacted by the ICD 10 changes.
9. SACs and/or Workgroups will decide to eliminate all references to ICD 9 or update the ICD 10 translation on a case-by-case basis

CON Conversion to ICD 10

Process Timeline

September 2013
- Translation
- Drafting Language/Appendix Updates

December 2013
- Commission Proposed Action
- Public Hearing before March 2014

March 2014
- Commission Discussion & Final Action
- Delivery to JLC and Governor

May 2014
- Standards become effective

October 2014
- ICD 10 Implementation due date

CERTIFICATE OF NEED

3rd Quarter Compliance Report to the CON Commission

October 1, 2012 through September 30, 2013 (FY 2013)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	3rd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	82	167
Approved projects contacted on or before anniversary date	58	121
Approved projects completed on or before 1-year follow up	72%	72%
CON approvals expired	35	73
Total follow up correspondence sent	239	539
Total approved projects still ongoing	328	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- Began statewide review of all mobile MRI networks based on the May 2013 MRI Service Utilization List, published by the Department.

- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has completed collection of information and investigation of the same. The Department is in the process of determining compliance remedies, drafting compliance orders, and arranging meetings with these providers to resolve these investigations.

- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. The Department has completed collection of information and investigation of the same. The Department is in the process of determining compliance remedies, drafting compliance orders, and arranging meetings with these providers to resolve these investigations.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED

3rd Quarter Program Activity Report to the CON Commission

October 1, 2012 through September 30, 2013 (FY 2013)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	116	N/A	326	N/A
Letters of Intent Processed within 15 days	114	98%	324	99%
Letters of Intent Processed Online	116	100%	326	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	98	N/A	252	N/A
Applications Processed within 15 Days	98	100%	252	100%
Applications Incomplete/More Information Needed	73	74%	181	72%
Applications Filed Online*	88	100%	220	100%
Application Fees Received Online*	21	24%	48	19%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	27	100%	96	100%
Substantive Applications	37	100%	96	100%
Comparative Applications	3	100%	9	100%

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	2	N/A	4	N/A
Decisions Issued within 10 workings Days	2	100%	4	100%

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	23	100%	64	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	3rd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	30	N/A	115	N/A
FOIA Requests Processed on Time	30	100%	115	100%
Number of Applications Viewed Onsite	0	N/A	2	N/A

FOIA – Freedom of Information Act.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(9.6.13)

Case Name	Date Opened	Case Description	Status
Medilodge of Livingston v MDCH, et al Macomb County Circuit Court *Livingston – Compare Group* *#95-0214* Includes: *Medilodge of Livingston – CON App # 11-0044* *Livingston Care Center – CON App # 11-0021*	09/14/12	Appeal of the MDCH Director's final decision.	On 4/3/13, the Livingston County Circuit Court transferred the case back to Macomb County. The matter has been briefed and oral argument is scheduled for 9/30/13.
Case Name	Date Opened	Case Description	Status
Medilodge of St. Clair v MDCH, et al St. Clair County Circuit Court *St. Clair – Compare Group* *#95-0217* Includes: *Medilodge of St. Clair – CON App # 11-0032* *Regency on Lk- Ft. Gratiot – CON App # 11-0034*	09/14/12	Appeal of the MDCH Director's final decision.	There was a delay in getting the tribunal record to Circuit Court. Oral argument was heard on 9/6/13. Judge took the matter under advisement and will issue a written decision.

CERTIFICATE OF NEED LEGAL ACTION

(9.6.13)

Case Name	Date Opened	Case Description	Status
Medilodge of Oxford, et al v MDCH, et al Michigan Court of Appeals No. 315526 *Oakland – Compare Group #95-0217* Includes: *Medilodge of Oxford – CON App # 11-0045* *Medilodge of Clarkston – CON App # 11-0043* *Medilodge of Square Lk – CON App # 11-0041* *Regency on the Lk – CON App # 11-0033* *Manor of Farm. Hills – CON App # 11-0024* *Bloomfield Orchard – CON App # 11-0028* *Sen. Com. Of Auburn Hills – CON App # 11-0023* *Sen. Com. Of Prov. Pk. – CON App # 11-0022*	04/02/13	Application for Leave to Appeal the Circuit Court's 3/12/13 order affirming the Department's decision and dismissing the appeal.	On 4/1/13, the Medilodge entities filed an application for leave to appeal with the Michigan Court of Appeals. The Department, Bloomfield Orchard Villa and Manor of Farmington Hills filed responses. We are waiting for a decision from the Court of Appeals as to whether it will grant or deny the application.
Case Name	Date Opened	Case Description	Status
Mercy Memorial Nursing Center - CON App # 12-0307	3/11/13	Monroe County – Denial of application seeking nursing home beds – Administrative Appeal	Mercy Memorial amended its application to reduce the number of beds sought and to comply with the existing bed need for the planning area. If MDCH approves the amended application, the matter will be dismissed.

CERTIFICATE OF NEED LEGAL ACTION

(9.6.13)

Case Name	Date Opened	Case Description	Status
Pontiac Osteopathic Hospital dba McLaren Oakland Oakland County Circuit Court Includes: CON App # 12-0024 and 12-0025	6/20/13	Appeal of the MDCH Director's final decision.	McLaren filed its brief on appeal on 8/28/13. MDCH's brief is due 9/18/13.
St. Mary's Nursing & Rehab Center, aka St. Mary's Acquisition, Inc. Includes: CON App # 13-0041 and 13-0042 Compare Group: 95-0236	8/26/13	Macomb County – Comparative review of nursing home beds – administrative appeal CON App. #13-0041 (Shelby Nursing Center) was approved for 12 new beds; St. Mary's was denied based on more beds being requested than available.	Prehearing is scheduled for 10/10/13 @ 9:00 am

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

Attachment N

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2012												2013											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Air Ambulance Services**										PC	•	•	•R	•	•R	•	•	•	•	•	• R—			
Cardiac Catheterization Services																					•	• PC	•	• R—1
Computed Tomography (CT) Scanner Services**										PC	•	•	•R	•	•	•	•	•	•	•	• R—	•	•P	•▲ F
Hospital Beds																					•	• PC	•	• R—1
Magnetic Resonance Imaging (MRI) Services	•R	•	•R —S	•S	•PS	•▲ F•S	•S	•	•	•	•	•	•	•	•R —	•	•P	• ▲F						
Megavoltage Radiation Therapy (MRT) Services/Units																						PC		
Neonatal Intensive Care Services/Beds (NICU)**										PC	•	•	•R	•	•	•	•	•	•	•	• R—	•	•P	•▲ F
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups**										PC	•	•	•R	•	•S	•S	•S	•S	•	•	•	•	•	•
Open Heart Surgery Services	•S	•S	•S	▉	▉	▉	▉	▉	▉	▉	•	•R —	•	•	• R—	•	•	• R—	• P	•	• ▲F	• PC	•	• R—1
Positron Emission Tomography (PET) Scanner Services																						• PC	•	• R—1
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units**										PC	•	•	•R	•	•	•	•	•	•	•	• R	•	•	• R—1
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M
CON Annual Activity Report FY 2013																								R

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▉ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
1 ICD-10 Translation

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PC - Public Comment Period for initial comments on review standards for review in the upcoming year
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval September 17, 2013

Updated August 8, 2013

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Policy & Planning, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2016
Bone Marrow Transplantation Services	December 3, 2010	2015
Cardiac Catheterization Services	February 27, 2012	2014
Computed Tomography (CT) Scanner Services	February 27, 2012	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	September 28, 2012	2014
Magnetic Resonance Imaging (MRI) Services	September 28, 2012	2015
Megavoltage Radiation Therapy (MRT) Services/Units	November 21, 2011	2014
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	February 25, 2008	2014
Positron Emission Tomography (PET) Scanner Services	September 28, 2012	2014
Psychiatric Beds and Services	November 5, 2009	2015
Surgical Services	February 27, 2012	2014
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2016

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.

Note: Pancreas Transplantation services are no longer subject to and no longer require CON approval effective September 28, 2012.