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 8 **UNITED STATES DISTRICT COURT**
 9 **NORTHERN DISTRICT OF CALIFORNIA**

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MARCIANO PLATA, et al.,

Plaintiffs,

v.

ARNOLD SCHWARZENEGGER, et al.,

Defendants.

Case No. C01-1351 TEH

**NOTICE OF FILING OF REPORT AND
 RESPONSE OF RECEIVER
 REGARDING PLAINTIFFS' MOTION
 RE VALLEY FEVER**

**Hearing Date: June 17, 2013
 Time: 10:00 a.m.**

TO THE COURT AND ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on May 1, 2013, Receiver J. Clark Kelso filed his Report and Response Regarding Plaintiffs' Motion Re Valley Fever ("Report"), a copy of which is attached hereto. The Report has been filed pursuant to the Court's Order, dated March 21, 2013.

Dated: May 1, 2013

FUTTERMAN DUPREE DODD
 CROLEY MAIER LLP

By: /s/Martin H. Dodd
 Martin H. Dodd
 Attorneys for Receiver J. Clark Kelso

**REPORT AND RESPONSE OF RECEIVER REGARDING
PLAINTIFFS' MOTION RE VALLEY FEVER**

**Report Submitted Pursuant To Court Order,
Dated March 21, 2013**

**Hearing Date
June 17, 2013
10:00 A.M.**

**California Correctional Health Care Services
J. Clark Kelso, Receiver**

INTRODUCTION

On March 20, 2013, Plaintiffs filed a motion for an order requiring the Defendants, after consultation with the court experts, to take the following steps, among others, in response to Coccidioidmycosis (“cocci” or “Valley Fever”)-related morbidity and death in prisons in the Southern San Joaquin Valley: suspension of the transfer of African-Americans, persons with diabetes, HIV or any immunocompromised state or inmates without HIV test results to Pleasant Valley State Prison (“PVSP”) and Avenal State Prison (“ASP”). On March 21, 2013, this Court ordered the parties to meet and confer under the auspices of the Receiver regarding the Plaintiffs’ motion and, if possible, to file a stipulation resolving or narrowing the issues by April 24, 2013. In the event that any issues pertaining to the motion remained unresolved, the Defendants were instructed to file any opposition to the motion by May 6, 2013 and Plaintiffs were instructed to file a reply by May 13, 2013. The court experts were directed to file a report and recommendations by no later than May 24, 2013. The Court also granted leave to the Receiver to file a response to Plaintiffs’ motion by on or before May 24.

On April 15, 2013, the Receiver convened a meet and confer session with the parties to discuss Plaintiffs’ motion. The parties were unable to reach agreement at the meet and confer session. On April 29, 2013, subject to any modifications which this Court may require, the Receiver promulgated, and notified the parties of, a Cocci Exclusion Policy and is seeking the Defendants’ cooperation in implementing it. After consulting with the Court’s experts and conducting a further statistical examination, on May 1, 2013, the Receiver amended the Cocci Exclusion Policy by adding to the list of those excluded from ASP and PVSP inmates diagnosed with diabetes mellitus. The Receiver has adopted and amended the policy in advance of May 6,

2013 to provide the Defendants with an opportunity to review and comment upon it in any opposition to Plaintiffs' motion Defendants may file.

The policy provides as follows:

“Cocci Exclusion Policy (May 1, 2013)”

“To reduce the risks associated with cocci disease at PVSP and ASP to a reasonable level, the following inmates shall be excluded from PVSP and ASP (except for those inmates who waive the application of this exclusion policy):

- (1) inmates who, considering all available patient information, are at an increased risk for contracting cocci disease of 50 percent or greater than baseline risk; and
- (2) inmates who, considering all available patient information, would be at a significantly increased risk of morbidity and/or mortality from contracting cocci disease, which includes inmates who are
 - a. medical high-risk;
 - b. HIV infected;
 - c. immunocompromised;
 - d. diagnosed with diabetes mellitus;
 - e. undergoing immunosuppressive chemotherapy; or,
 - f. pregnant.”

**RATIONALE FOR AND DEVELOPMENT OF THE NEWLY PROMULGATED
COCCI EXCLUSION POLICY**

A. Background

1. Analyses of, and Efforts to Address, Valley Fever Prior to April 2013

Since at least 2006, following publication of a formal study and report on cocci by the California State Public Health Department (“SPHD”), the California Department of Correction and Rehabilitation (“CDCR”) has been contemplating how to address cocci at Central Valley prisons, including particularly PVSP and ASP. As a result of the SPHD study, CDCR implemented a program intended to reduce cocci by: (1) excluding inmates most vulnerable to cocci complications (*i.e.*, those with HIV infection, immunosuppression, and chronic lung

disease requiring oxygen therapy) from eight institutions in the cocci hyperendemic area; (2) educating inmates about cocci symptoms; and (3) canceling certain planned construction at PVSP. Unfortunately, these efforts failed to reduce cocci rates. A study prepared by California Correctional Health Care Services (“CCHCS”) and SPHD showed that during 2006-2010 cocci rates in the hyperendemic area had failed to decline and, therefore, made additional recommendations for reducing the incidence of cocci among inmates in the hyperendemic area.

One of those recommendations was to implement environmental mitigation measures at PVSP to reduce cocci in the ambient air. Accordingly, in 2011, with funding provided by the Receiver, CDCR undertook a soil stabilization program on some of the unpaved surfaces at PVSP. The Receiver did not immediately implement or urge the implementation of the other recommendations in the report in the hope that reducing the spread of dust alone would materially reduce the incidence of Valley Fever. In September 2012, the Prison Law Office (“PLO”) brought to the Receiver’s attention that an April 2012 study of the measures adopted by CDCR since the release of the SPHD 2006 report had been unsuccessful in significantly reducing the rates of cocci or the morbidity and mortality among the inmate population. The Receiver immediately notified CDCR leadership of the information. The Receiver and CDCR discussed, among other things, the advisability of requesting technical assistance from the Centers for Disease Control (“CDC”) and the National Institute for Occupational Safety & Health (“NIOSH”), the possible use of a skin-test to determine which inmates were most at risk of contracting cocci, and whether to expand the list of exclusions to include African-Americans.

In or around March 2013, CDCR did attempt certain mitigation measures at PVSP and ASP, including installing equipment on the doors at all housing units designed to keep out dust and a finer air filter in one housing unit at each institution. Other than these mitigation efforts,

however, and despite repeated expressions of serious concern by the PLO since at least the latter half of 2012, CDCR has moved only slowly to develop a plan for responding to the ongoing cocci problem at PVSP and ASP, in particular. CDCR did not promptly contact either the CDC or NIOSH for assistance and even waited several months before formally contacting its own public health officials at SPHD. Even then, CDCR requested only narrow assistance from SPHD. During this period, although the State had available to it the full resources of its own public health officials and could have contracted for any additional assistance it may have needed, the State failed to conduct any further analysis of the available data on either the incidence of cocci or mitigation strategies.

In the face of the State's anemic response, the Receiver undertook his own analysis to address the cocci issue and, among other things, requested assistance from CDC and NIOSH.¹ Within days, CDC and NIOSH staff contacted the Receiver to begin determining what resources would be necessary and available for this analysis.

2. Reports and Analyses Commissioned by the Receiver in April 2013

Long-standing research on cocci has consistently shown that certain ethnic or racial groups, and especially African-Americans, are more susceptible to contracting cocci than other groups. While categorical exclusion of such ethnic or racial groups from prisons in the hyperendemic area is one strategy which could be employed to respond to cocci, the Receiver was reluctant to add a race-based classification to the list of exclusions without further analysis. The Receiver requested that his staff investigate whether an exclusion policy could be based on a risk-basis (*i.e.*, the risks of contracting cocci and of developing severe cocci) so that any

¹ SPHD officials eventually joined the Receiver's request to CDC and NIOSH for assistance.

exclusion policy need not be based solely on racial classifications. Those efforts quickly demonstrated that such a risk-based policy is feasible.

April 11, 2013 Report

On April 11, 2013, the Receiver's public health staff presented him with an analysis and report which is set forth in full below:

"Methods:

"To determine risk factors for cocci disease in our inmate population at ASP and PVSP we compared 525 patients with cocci with illness onsets in 2011 who were diagnosed at ASP or PVSP and compared them with 15,209 persons who resided at ASP or PVSP who did not develop cocci in 2011 and who had not been diagnosed with cocci prior to 2011. We found that African Americans, Latinos and race/ethnicity of "other" had a higher risk of cocci compared with whites (after controlling for age group, location of residence (ASP or PVSP), and for chronic diseases). We found that older age-groups had a higher risk of cocci disease compared with age ≤ 35 years (after controlling for race/ethnicity, residence and chronic disease). We found no association between cocci disease and any of these chronic diseases: diabetes, asthma, COPD, cardiac disease (exclusive of HTN), renal insufficiency or failure, hepatitis C, and hepatitis C on treatment. We found an association between cancer chemotherapy and cocci but there were only 2 patients with cocci in this group (in 2011) and no patients on cancer chemotherapy now reside at ASP and PVSP.

"Table 1

Possible Exclusion Criteria	Percent of Population at PVSP and ASP	Relative Risk (95% Confidence Interval)	Comparison Group	Increased Risk Percent for cocci disease
African American	24%	1.9 (1.5-2.4)	White	90% increased risk
Latino/Hispanic	42%	1.3 (1.1-1.7)	White	30% increased risk
Other race	5%	2.0 (1.3-3.0)	White	100% increased risk
Age 36-55 years	47%	1.4 (1.1-1.6)	17-35 years	40% increased risk
Age ≥ 56 years	9%	1.6 (1.2-2.2)	17-35 years	60% increased risk
Diabetes	8%	1.1 (0.8-1.5)	No diabetes	No significant increased risk
HIV infected/immuno-compromised	0%	NA	NA	Already excluded

“*Note: we are currently evaluating the proportion of patients at ASP and PVSP with an unknown HIV infection status. In our evaluation of the opt-out HIV screening program, we found that 77% of new entrants to CDCR accepted HIV screening in 2012.”²

“We are currently evaluating risk factors for severe disease (hospitalization) by comparing patients with cocci with no hospitalization (in the year after their diagnosis) with those with at least one hospitalization. We are evaluating risk factors for disseminated disease in our population by comparing patients with hospitalizations for disseminated disease with those who have not been hospitalized for the year after their diagnosis.

“With any combination of exclusion criteria a high proportion of inmates would be transferred out of PVSP and ASP. One option for back filling the vacated beds is to evaluate inmates diagnosed with cocci who now reside in prisons other than ASP and PVSP for placement into ASP or PVSP. Inmates who are classified as medium risk who have had cocci disease and now have chronic conditions under good control could also be considered for placement into ASP and PVSP.”³

Draft Cocci Exclusion Policy

At the meet and confer session on April 15, 2013, the Receiver provided the parties with a draft “Proposed Cocci Exclusion Policy,” which had been developed based on the analysis of risk factors undertaken by the Receiver’s staff, and which expanded the list of excluded groups effectively to include African-Americans, Filipinos, Small Group of “Other” Races, and Inmates Over 55 Years of Age. The text of the proposed policy was very similar to the final Cocci Exclusion Policy.⁴ Meanwhile, the Receiver’s public health staff continued its analysis to

² These additional analyses are ongoing and should be able to be completed relatively soon. The best available data suggests that as many as 50% of the inmates at PVSP and ASP have not been tested for HIV. These inmates are being offered HIV testing.

³ While backfilling beds with inmates who currently have or have had cocci may seem counterintuitive, the rationale is as follows: if an inmate already has or had cocci he has lifelong immunity and is unlikely to get a second episode. As a result, if his general medical needs are appropriate for the care available at PVSP or ASP, it would be safe from a medical standpoint to house that inmate at either institution.

⁴ The primary difference between the draft policy and the April 29, 2013, Cocci Exclusion Policy is that the draft policy applied to inmates with diabetes, while the April 29 policy did not. This

identify the risk factors for contracting severe cocci (*i.e.*, requiring hospitalization) and to determine whether and to what extent such risk factors would require further modifications to the exclusion policy.

April 26, 2013 Report

On April 26, 2013, the Receiver's staff presented the results of its further analysis, which is quoted at length below:

“Risk for severe and disseminated coccidioidomycosis, 4/26/13

“To assist with developing a strategy to prevent morbidity due to cocci at PVSP and ASP using expanded exclusion criteria, we conducted an analysis to determine demographic risk factors for severe cocci disease (without dissemination) and for disseminated cocci disease. In an earlier analysis we determined risk factors for cocci disease; in this analysis we sought to determine factors associated with high morbidity among persons after developing cocci disease.

“Methods

“We compared 474 patients with cocci diagnosed in 2011 at ASP or PVSP who have not been hospitalized through 4/11/2013 to: 1) 115 patients with cocci who were hospitalized from 7/1/10 through 4/11/13 for more than 10 days and had non-disseminated cocci (ICD 9 codes 114.0 or 114.4–114.9)⁵ and 2) 115 cocci patients hospitalized from 7/1/10 through 4/11/13 with disseminated cocci (ICD 9 codes 114.1, 114.2, or 114.3).

“We analyzed risk by race/ethnicity (African American, Asian-Pacific Islander, Filipino, Hispanic, other, compared with white) and age (as a continuous variable). We used SAS 9.2 to analyze the data and set the p-value for statistical significance at ≤ 0.05 .

“Results

was based on the absence of any statistical support in our analysis that diabetes was a risk factor for contracting cocci. Subsequent analysis establishes that diabetes is in fact a risk factor for an inmate developing a more severe reaction to cocci, which is why the Receiver amended the policy on May 1 to include diabetes as an exclusionary category.

⁵ “ICD 9” is the Ninth Revision of the International Classification of Diseases, a list of diagnoses used to categorize patients who have been in a clinical setting (such as a hospital). The classification can be used to identify patients with a particular diagnosis or to bill for treatment/care of a patient with a specific diagnosis.

“We found that:

- Of non-hospitalized patients with cocci 32% were African American, of patients with severe cocci 36% were African American, and of patients with disseminated cocci 50% were African American;
- **Neither age nor race/ethnicity** was associated with severe coccidioidomycosis;
- **African Americans** had a 90% higher risk of disseminated disease compared with whites, after controlling for age (OR= 1.9; 95% CI=1.1-3.4). **No other race/ethnicity** was associated with increased risk for dissemination as compared to whites. **Age** was not associated with increased risk of dissemination.

“**Next Steps:**

- 1) We will assess for interaction in our models of risk factors for cocci, severe, and disseminated cocci.
- 2) We will determine the attributable risk of demographic factors on cocci and disseminated cocci; this analysis will permit us to predict the decrease in morbidity expected when inmates with specific risk factors (e.g., African American race and older age) are excluded from PVSP and ASP.”

May 1, 2013 Report

After promulgating the Cocci Exclusion Policy on April 29, 2013, the Receiver consulted again with the Court’s experts. The experts requested that the Receiver reconsider the decision to drop inmates with diabetes from the exclusion policy. In response, the Receiver directed his staff to analyze the data to determine whether inmates with diabetes were at a higher risk of developing more severe forms of the disease than others. That analysis demonstrates that, while being diabetic is not associated with either a higher risk of contracting cocci or a higher risk of developing disseminated cocci, it is associated with a higher risk of more lengthy hospitalization, primarily because of greater difficulty in treating damage to the lungs associated with cocci. The staff analysis is as follows:

“Risk for severe and disseminated coccidioidomycosis, 5/1/13 (note this is updated from 4/26/13 by including diabetes mellitus in the analyses)

“To assist with developing a strategy to prevent morbidity due to cocci at PVSP and ASP using expanded exclusion criteria, we conducted an analysis to determine risk factors for severe cocci disease (without dissemination) and for disseminated cocci disease. In an earlier analysis we determined risk factors for cocci disease; in this analysis we sought to determine factors associated with high morbidity among persons after developing cocci disease.

“Methods

“We compared 474 patients with cocci diagnosed in 2011 at ASP or PVSP who have not been hospitalized through 4/11/2013 to: 1) 115 patients with cocci who were hospitalized from 7/1/10 through 4/11/13 for more than 10 days and had non-disseminated cocci (ICD 9 codes 114.0 or 114.4–114.9) and 2) 115 cocci patients hospitalized from 7/1/10 through 4/11/13 with disseminated cocci (ICD 9 codes 114.1, 114.2, or 114.3).

“We analyzed risk by race/ethnicity (African American, Asian-Pacific Islander, Filipino, Hispanic, other, compared with white), age (as a continuous variable) and diabetes mellitus (compared with no diabetes mellitus). We used SAS 9.2 to analyze the data and set the p-value for statistical significance at ≤ 0.05 .

“Results

“We found that:

- Of non-hospitalized patients with cocci 32% were African American, of patients with severe cocci 36% were African American, and of patients with disseminated cocci 50% were African American;
- Of non-hospitalized patients with cocci 8% had diabetes mellitus (DM), of patients with severe cocci 22% had DM, and of patients with disseminated cocci 8% had DM.
- **Diabetes mellitus** was associated with a 220% increased risk of severe disease compared with those without DM (OR=3.2, 95% CI= 1.8-5.8). Neither age nor race/ethnicity was associated with severe coccidioidomycosis;
- **African Americans** had a 90% higher risk of disseminated disease compared with whites, after controlling for age (OR= 1.9; 95% CI=1.1-3.4). Age, race/ethnicities other than African American and DM were not associated with disseminated cocci.”

B. Impact Of The Receiver’s Analyses On The Development Of The Newly Promulgated Cocci Exclusion Policy

Based on all of the information available to the Receiver, including the most recent analyses by Receivership staff, as of May 1, 2013, the newly promulgated Cocci Exclusion

Policy (May 1, 2013) applies, according to paragraph (1), to all inmates shown to be at a 50% or greater increased risk (above baseline) of contracting cocci.

The April 11 analysis prepared by the Receiver's staff showed that the risk for contracting cocci disease varied by race/ethnicity (with whites as a baseline) and age (with inmates younger than 36 as a baseline). As Table 1 reflects, the increase in risk ranges from 30% to more than 100%, with different groups showing different rates of increase as follows: +30% (Latino/Hispanic), +40% (Age 36-55), +60% (Age > 55), +90% (African-American), and +100% (Other race).

The Receiver decided to exclude, as a matter of policy, inmates with an increased risk of 50% or more, rather than all inmates with any increased risk. Two reasons support this conclusion. First, the confidence intervals for the categories below 50% (*i.e.*, Age 36-55 and Latino/Hispanic) range from 1.1 to 1.6/1.7. In other words, at the low end of the confidence interval, there is only a 10% increased risk over baseline, which the Receiver concluded is comparatively insignificant, particularly since the upper end of the confidence interval is only slightly above the 50% line. By contrast, the upper end of the confidence intervals for categories above 50% (*i.e.*, African-American, Other race, and Age > 55) are all greater than 2.0 (*i.e.*, double the risk of the baseline)), and at the lower end of the confidence intervals are 20%, 30% and 50% above the baseline, respectively. These results suggest that drawing the line at 50% represents a rational way of dealing with any uncertainties in the data and that there is a natural break-point around 50%. Second, the April 26 report on severe and disseminated cocci showed that African-Americans, but no other racial group, had a significantly increased risk for disseminated cocci. This supports the decision to draw a line that, as a practical matter, excludes African-Americans but does not categorically exclude Latino/Hispanic inmates.

Finally, the version of the exclusion policy presented to the parties on April 15 would have categorically excluded inmates with diabetes mellitus.⁶ The April 29 policy dropped that categorical exclusion because the data collected and analyzed by the Receiver's staff as of that date did not support its inclusion. After reconsidering the issue in light of additional statistical analysis, it is clear that inmates with diabetes mellitus are at an increased risk for hospitalizations from cocci, and the Receiver amended the policy on May 1, 2013, to restore this categorical exclusion.

CONCLUSION

In conclusion, based on the analyses recently performed by the Receiver's staff, the Cocci Exclusion Policy promulgated on April 29, 2013, as amended on May 1, 2013, applies to those inmates falling into groups with a risk of contracting cocci of 50% or more above baseline, as well as inmates characterized as (1) medical high risk; (2) HIV infected; (3) immunocompromised; (4) diagnosed with diabetes mellitus; (5) undergoing immunosuppressive chemotherapy; or (6) pregnant.

Dated: May _1_, 2013



J. Clark Kelso, Receiver

⁶ The other categorical exclusions are for inmates who are classified as medical high-risk, are HIV infected, immunocompromised, undergoing immunosuppressive chemotherapy, or pregnant.